FEDERAL TRADE COMMISSION

I N D E X (PUBLIC RECORD)

FEDERAL TRADE COMMISSION

In the Matter of:	)
SCHERING-PLOUGH CORPORATION,	)
a corporation,	)
and	)
UPSHER-SMITH LABORATORIES,	) File No. D09297
a corporation,	)
and	)
AMERICAN HOME PRODUCTS,	)
a corporation.	)
----------	)

Wednesday, January 23, 2002

11:17 a.m.

TRIAL VOLUME 1

PART 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

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P R O C E E D I N G S

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JUDGE CHAPPELL: I'm calling to order the trial or the hearing, docket 9297, in the matter of Schering-Plough, a corporation, Upsher-Smith Laboratories, Inc., a corporation, and American Home Products, a corporation.

At this time, for the record, I will take appearances of the parties. I'll take the Government first.

MS. BOKAT: Good morning, Your Honor. On behalf of complaint counsel, I am Karen Bokat. With me this morning at counsel table is Philip Eisenstat and our paralegal, Rachel Hertzman.

JUDGE CHAPPELL: Thank you. At this time I'll take the appearance of Schering-Plough.

MR. NIELDS: Thank you, Your Honor, and good morning. John Nields and Laura Shores on behalf of Schering-Plough.

JUDGE CHAPPELL: Okay. And now I'll take appearance of Upsher-Smith.

MR. CURRAN: Your Honor, I'm Christopher Curran. With me is Mark Gidley, Robert Paul, and as I mentioned earlier, Mr. Troup and Mr. Robbins are with us as well.

JUDGE CHAPPELL: Okay. Very briefly, a couple housekeeping matters I want to reiterate. I think we've discussed these before.

There are documents that have been introduced into evidence in this case which are pending motions for in camera treatment. I'm going to try to do this, and I want the parties to assist me, when you refer to a document or information with a witness or either in an argument to support an objection or a motion or any -- for any other reason, you need to let the Court know, you need to let the court reporter know, so we can have people leave the courtroom who are not subject to protective orders.

By the same token, when you have finished with the in camera matter, documents, stated information, whatever, you also need to let the Court know, because our court reporter has a different transcript running for in camera matters.

Any questions on that?

MS. BOKAT: No, Your Honor.

MR. NIELDS: No, Your Honor.

MR. CURRAN: No, Your Honor.

JUDGE CHAPPELL: Is the Government ready to proceed with their opening statement?

MS. BOKAT: Yes, we are, Your Honor.

JUDGE CHAPPELL: Ms. Bokat, you may begin.

MS. BOKAT: Thank you.

This case is about a plan between a branded drug manufacturer and its generic competitors to divide a market for a drug. Schering-Plough made illegal payments to Upsher-Smith and ESI Lederle to delay entry of their competing products into the market. By delaying competition, Schering protected its profits. Each day of delay, however, harmed consumers, because they were forced to continue paying higher prices than they would have otherwise. Those two facts, an agreement among competitors to divide the market and harm to consumers, add up to a violation of Section 5 of the Federal Trade Commission Act.

I'm Karen Bokat. I'm going to give you a preview this morning of what complaint counsel will prove in this case.

Schering-Plough is a large drug company that manufactures a drug product under the brand name K-Dur 20. K-Dur 20 is a 20 milliequivalent potassium chloride tablet. Twenty milliequivalents is simply a way of referring to the dosage strength in a tablet.

Potassium chloride supplements are used to treat patients who have low potassium levels. This occurs frequently in people who have high blood

pressure and have to take drugs for the blood pressure that deplete potassium. They then need to take potassium supplements, because having potassium that is too low can lead to fatigue, muscle weakness and serious heart problems.

In 1995, Schering had a monopoly on the 20 milliequivalent sustained release potassium chloride capsules and tablets. No other manufacturer marketed in the United States a 20 milliequivalent potassium chloride tablet. Sales of K-Dur 20 in 1995 were over $100 million, and 80 percent of those revenues represented profits to Schering.

However, Upsher-Smith and ESI Lederle had developed generic versions of K-Dur 20 that would compete directly with Schering's product. Once either Upsher or ESI's product entered the market, priced well below K-Dur 20, it would draw sales away from Schering's product and eat into Schering's revenues.

Schering held a patent related to K-Dur 20 and, in fact, still holds that patent, so it sued Upsher-Smith and ESI for patent infringement. On June 17th, on the eve of the trial in the patent litigation between Schering and Upsher-Smith, those two companies entered into an agreement whereby Schering would pay Upsher-Smith $60 million, and Upsher-Smith would not

bring its generic to market until September 2001.

We will pause for a moment and look at that agreement, because it's probably the single most important document in this case.

May I approach the Bench and offer Your Honor a copy of this CX in case you want to follow along?

JUDGE CHAPPELL: Right, and just so we're clear, you're going to refer only to documents that have been admitted into evidence in your opening statement. Is that correct?

MS. BOKAT: That's right, and my opening statement should include no in camera documents.

JUDGE CHAPPELL: Okay, the agreement is not in camera?

MS. BOKAT: No.

JUDGE CHAPPELL: Okay, you may approach.

MS. BOKAT: Thank you, Your Honor.

JUDGE CHAPPELL: Ms. Bokat, while we're at this point here, I didn't want to interrupt you, but I wanted to let the parties know I have thoroughly reviewed and read the trial briefs, and I want to compliment the parties, all the parties. Everyone did a very good job, excellent job with your trial briefs. Thank you.

MS. BOKAT: Thank you, Your Honor.

MR. CURRAN: Thank you, Your Honor.

MS. BOKAT: This agreement between Schering-Plough and Upsher-Smith is dated June 17th, 1997. It was executed on behalf of both Schering-Plough and Upsher-Smith. We're going to look first at paragraph number 3 of this agreement, which contains Upsher-Smith's commitment to keep its generic of K-Dur 20 off the market until September 2001. There's a reference in this paragraph to Klor Con M20. That's the name Upsher planned to use for its generic of K-Dur 20.

In this paragraph, Upsher-Smith agreed, and I will quote, "Upsher-Smith agrees that it will not market in the United States its Klor Con M20 potassium chloride product, or any other sustained release microencapsulated potassium chloride product, prior to September 1, 2001." So, in other words, Upsher-Smith was agreeing to keep off the market not only the generic which Schering had sued, but any other microencapsulated potassium chloride product as well.

Now, we will flip forward to paragraph 11, which contains Schering's commitment to compensate Upsher-Smith. The introductory clause to this paragraph reads, "In consideration for the licenses, rights and obligations described in paragraphs 1

through 10 above, SP Licensee shall make the following payments to Upsher-Smith." So, in other words, these payments are for paragraphs 1 through 10, which, of course, includes paragraph number 3 in which Upsher committed to hold its generic off the market until September 2001.

Schering committed to make an initial payment of $28 million 48 hours after Schering's board approved this agreement. Schering was to make a second payment of $20 million one year after board approval and a third payment of $12 million on the second anniversary of board approval.

A little later, Schering entered into an agreement with the other company that had developed a generic for K-Dur 20, ESI Lederle, a subsidiary of American Home Products, Incorporated. Schering agreed to pay $5 million almost immediately and up to another $10 million depending on if and how soon ESI received from the Food and Drug Administration tentative approval of their generic. In other words, the sooner that ESI got over the regulatory hurdle and got that much closer to being able to come to market, the more money it would receive from Schering-Plough. ESI agreed to withhold its generic from the market until January 2004, and this agreement was entered into in

1998.

Both of these agreements are anti-competitive and illegal because they delayed competition, kept prices substantially higher than they would have been otherwise and harmed consumers. That's what this case is about. It's not a patent case. It's an antitrust case. We will prove that respondents entered into illegal agreements. We will prove that through respondents' own documents, through the testimony of respondents' officials and employees and through our own witnesses.

I would like to focus first on Schering's monopoly. Potassium chloride is an old product that has long been used to treat patients with low potassium levels, but Schering-Plough developed a sustained release technology that it applied to K-Dur 20. This is a K-Dur 20 tablet. It has clear advantages over other potassium chloride supplements, because with this sustained release technology, potassium is released into the body gradually over a day.

JUDGE CHAPPELL: For the record, Ms. Bokat is holding a white tablet in her hand.

MS. BOKAT: Older potassium chloride supplements, when the potassium is released, it tends to clump, and those clumps can adhere to the lining of

the stomach and intestine, potentially causing ulcers. K-Dur 20 does not pose that problem to the GI tract because of this slow release technology that Schering developed.

K-Dur 20 also has the advantage of packing 20 milliequivalents of potassium into one tablet. So, for patients who need to take 20 or more milliequivalents a day, they can get the potassium they need by taking fewer pills, and we find that patients are more likely to conform to what the physician's prescribed if they don't have to take as many pills.

Schering had a good thing going. Back in the mid-1990s, there was no competitive 20 milliequivalent potassium chloride tablet on the market. K-Dur 20's sales grew every year in the mid-1990s. We have an illustrative we prepared to show this point. You'll see that this covers the period from 1995 through the year 2000, and each year the dollar sales of K-Dur 20 were increasing. In fact, by 1996, those sales had reached $153.6 million. Most of those sales were profits to Schering, approximately 80 percent.

This second illustration for those same years, 1995 through 2000, shows sales in the gray bars and profits in the red bars. Oh, I should point out, Your Honor, that this illustration of sales and profits is

for all of K-Dur, which includes the 10 as well as the 20 milliequivalent strength, but the preponderance of the sales, over 90 percent, are, in fact, K-Dur 20.

JUDGE CHAPPELL: That exhibit says -- the orange is product margin?

MS. BOKAT: These are the profit margins on the product.

JUDGE CHAPPELL: And this is not evidence, unless it's already been admitted, but -- so, it's mislabeled, it's not product margin, it's profit margin?

MS. BOKAT: It probably would have been clearer if we had labeled it that way, and it might be a good idea to have this relabeled.

JUDGE CHAPPELL: Mr. Nields?

MR. NIELDS: I would have objected if they labeled it profit, Your Honor. It's not profit. It's product margin.

JUDGE CHAPPELL: Just so we're clear, this is opening statement, this is not evidence, so with that in mind, proceed.

MS. BOKAT: Thank you, Your Honor.

But as soon as another firm developed a generic of K-Dur 20, Schering would face the loss of its monopoly power. What does a branded manufacturer fear

the most? Generic entry. After a generic enters the market, the branded product cannot hold onto its old sales volume, because there are several forces at work in the market that tend to shift sales from the branded product to the generic.

The first is that in several states, laws permit the pharmacist to dispense a generic in place of the branded product without having to call the physician for authorization unless the physician explicitly notes on the prescription that it must be dispensed as written. The second is that many prescription drug plans have incentives built into them to use the generic in place of the brand. And third, for patients who have no prescription drug coverage and have to pay the full price of their prescriptions out of their pockets, there's a strong incentive to purchase the lower cost generic in place of the brand.

Generic competition eliminates the brand's monopoly power. The brand loses significant dollar sales if consumers switch to the lower cost generic. Some of those dollars go to the generic competitor. Some of it represents savings to consumers. Consumers benefit substantially from having generics available to them. We don't have to rely on economic theory for that proposition, although economic theory

substantially supports it.

The evidence will show that Upsher, now that it is finally selling the generic, prices their product almost 50 percent below K-Dur's price. Consumers have finally benefitted from competition since Upsher entered the market.

We have prepared a series of three pie charts to illustrate these points. The first pie illustrates the monopoly situation where all the revenues go to the monopolist. The second pie illustrates the competitive situation. There are still sales to the incumbent but substantially smaller than we saw in the monopoly pie. There's sales to the entrant and savings to consumers. The third pie illustrates what happens if the incumbent monopolist pays the entrant to stay off the market. There is revenue going to the entrant in the form of these payments, and the remainder stays with the incumbent, and the share's a lot larger for the incumbent than it would be in the competitive situation.

We can think about these pies in the context of the pharmaceutical industry. There, you would have the brand name product with a monopoly before it faces generic competition. Once generic competition arrives, some of the revenues go to the generic. The branded

revenues have shrunk substantially, and there are savings to consumers. The third pie is what happens if the brand pays the generic competitor to stay off the market. The sales go to the monopolist, some of it is passed through to the generic. So, we have revenues to the generic, but the great share of it remains with the monopolist.

These also illustrate what was prevailing in the 20 milliequivalent potassium chloride market. Prior to 1997, Schering had a monopoly, and all the revenues went to Schering. Once Schering entered into its agreement with Upsher and began making payments to Upsher, we had revenues going to Upsher. The remaining revenues stayed with Schering. We don't get to the competitive pie until September 2001 when Upsher finally entered. At that point, Schering's revenues shrank, Upsher had revenues, and at last, consumers had savings.

Schering's own documents will show that it recognized the threat of generic entry. As early as 1995, Schering anticipated that generic entry could occur in 1997, well before Schering's patent expired in the year 2006. Schering expected generic entry even before patent expiration because Schering's patent was a narrow one. It was not on potassium chloride, but

rather, on the sustained release technology. So, once the generic was able to develop a product with a different sustained release technology, it could enter the market.

I said earlier that we would prove this case through respondents' documents. I'll pause to take a look at a couple of them now.

Your Honor, the first is CX 13. May I approach the Bench and offer Your Honor a copy, please?

JUDGE CHAPPELL: You may; however, I can read it on the monitor. It's up to you.

MS. BOKAT: Okay, fine. We just wanted to have them available if you want.

JUDGE CHAPPELL: Thank you.

MS. BOKAT: Let me know, and I can always hand them out.

CX 13 is a memorandum that was written within Key Pharmaceuticals. Key Pharmaceuticals is the subsidiary of Schering-Plough responsible for the K-Dur product. That memorandum was written on March 8, 1995. The subject is "K-Dur Long-Term Strategy."

One of the issues that Schering flagged in its long-term strategy is generic competition to K-Dur 20 may come within two years, and because this memo was written in 1995, Schering anticipated there may be

generic competition as early as 1997. Not only did Schering flag this issue, but we will see through one of Schering's forecasts what it anticipated would happen to K-Dur sales once there was generic competition.

We are showing Your Honor a single page that comes from CX 122. We found that when we put the page up on the monitor, it was very difficult to read, so we have retyped it simply to make it more legible.

This forecast was prepared in March of 1996. It has actual data from 1995, the latest estimate for 1996 and forecast figures for 1997 through 2000. There are two lines of data on this page that are important for our discussion. The first is K-Dur, of course, the branded product, and the second, generic K-Dur.

Now, here, generic K-Dur, that line, is not talking about Upsher-Smith or ESI. Frequently, when a Schering branded product encounters generic competition from another company, Schering will actually introduce its own generic of its branded product, of course at a lower generic price, but for a manufacturer, this can be a way of retaining some of the unit sales.

So, we see here that the actual dollar sales of K-Dur in 1995 were $122 million, and Schering's estimate was that in 1996, that would grow to $140

million, but then beginning in 1997, the sales would drop off, falling between '96 and '97 from $140 million to $110 million, and then continuing to decline to $97 million in 1998, $68 million in 1999 and $52 million in the year 2000. Why? Well, if we look under the 1997 column at the Generic K-Dur line, we see Schering was expecting generic entry from another company followed by its own generic in 1997.

We also have an illustration we prepared drawing on two Schering K-Dur forecasts to show what Schering thought would be the difference in its sales with and without generic competition. The first forecast was prepared June 5th, 1997, which we see on that blue line. That date, of course, predates the Upsher-Smith agreement, so at that point, Schering was forecasting that K-Dur sales might drop off after 1998.

The second forecast, which we now see on that red line coming up, was prepared November 13th, 1997, so that's after the Schering-Upsher agreement was entered into. By that point, Schering knew it wouldn't face competition from Upsher before 2001. So, on that forecast line, we see the sales of K-Dur forecasted to continue to increase through the year 2000.

The prospect of losing significant sales to the generic gives the branded manufacturer an incentive to

pay the generic to stay off the market. Upsher and ESI were seeking approval to market generics of K-Dur 20. Both Upsher and ESI submitted applications to the Food and Drug Administration in 1995. Schering sued Upsher for patent infringement in 1995 and sued ESI in 1996.

Upsher received tentative approval of its generic from the Food and Drug Administration in March of 1997 and was preparing to come to market as early as the fall of 1997. The evidence will show that Schering entered into the agreement with Upsher to delay Upsher's entry and protect K-Dur 20's profits. Let's see how these two companies arrived at the agreement that we saw a few minutes ago.

Schering's own contemporaneous documents will tell us what was important to Schering and how Schering planned to structure the agreement with Upsher-Smith. The first of these is, again, CX 13, that 1995 memorandum we began looking at a few minutes ago. As I said earlier, Schering had flagged the issue of generic competition. Schering's objective in light of preventing generic competition was to maximize the length of time to introduction and minimize market penetration. Schering's strategy to address this issue? That has been redacted.

According to the privilege log, the redacted

material reflects legal advice on a legal strategy on protecting Schering's K-Dur 20 patent. There's another Schering document that will help us fill in that blank. It's called Executive Summary. This came to us from Schering's files, and it discusses settlement discussions with Upsher-Smith.

Schering realized that however it structured the agreement with Upsher, it was going to have to provide a revenue stream to Upsher-Smith. The document reads, "Additionally, any deal with Upsher-Smith should be lucrative and provide them with a guaranteed revenue stream of approximately $25-20 million per year until another K-Dur ANDA is approved. We could then allow Upsher-Smith to market their own product and discontinue any royalty stream after that time."

So, Schering was going to provide revenue to Upsher until Schering encountered generic competition from another company. So, however the revenue stream might be disguised, the quid pro quo was this: Money from Schering to Upsher so long as but only so long as Schering faced no generic competition in the market.

Schering calculated what selling its generic would be worth to Upsher-Smith and figured the net present value would be in the range of $45 to $55 million. That's the amount of revenue that Schering

would have to replace.

However, Schering knew that it couldn't simply pay Upsher-Smith, a competitor. It would have to disguise the transaction somehow. One way to disguise the payment would be to attach it to the purchase of Upsher products. As the memo says, among the options Schering was considering -- and here UPS refers to Upsher and SGP is Schering-Plough -- "Review UPS portfolio and purchase pipeline products or in-line portfolio for SGP to promote."

This executive summary foreshadows exactly what occurred. Schering agreed to pay $60 million to Upsher-Smith over two years. So, it was going to provide a revenue stream, and the net present value of $60 million over two years is about $55 million. And the payment was attached to licenses from Upsher-Smith.

In the brief time between May 21st and June 17th, 1997, less than one month, Schering and Upsher-Smith negotiated their agreement. The first negotiation meeting was held on May 21st, 1997, and as we saw earlier, the agreement is dated June 17th. The principal negotiators for the two companies were Ian Troup, president of Upsher-Smith, Martin Driscoll, vice president of sales and marketing for Key Pharmaceuticals, which is that subsidiary of

Schering-Plough responsible for K-Dur 20, and Raman Kapur, head of Schering's generic division.

The two sides were discussing when Upsher would be permitted to enter with its generic of K-Dur 20 as a way to settle the patent litigation. Mr. Troup told Mr. Driscoll that if Upsher delayed its entry, it would need replacement revenues. Remember, Upsher was projecting it might launch as early as the fall of 1997. Mr. Troup asked for $60 to $70 million. The way he came up with those figures he requested was he calculated the dollar sales volume that Schering's K-Dur 20 would lose to a generic competitor and then took a percentage of those lost revenues.

Ultimately, this is how the agreement was structured. Upsher agreed to delay until September 2001 bringing its generic for which Schering had sued them or any other microencapsulated product to market, and Schering agreed to pay Upsher $60 million. Schering did indeed pay Upsher the $60 million, and Upsher kept up its part of the bargain. It held its generic off the market until September 2001.

Now I would like to shift for a couple minutes to the other agreement, the agreement between Schering-Plough and ESI Lederle. Despite the agreement between Schering and Upsher-Smith, ESI was still a

competitive threat to Schering-Plough. It may help to understand Schering's incentive in entering into this agreement with ESI if I spend a couple minutes trying to explain the 180-day exclusivity period.

That exclusivity is intended for the first company to file an application with the Food and Drug Administration to sell a generic of a particular branded product. The 180-day exclusivity period begins to run when either the first filer begins selling its generic or there's a court decision in a patent litigation holding the patent is either invalid or not infringed.

The FDA may not approve a second generic until the 180-day period has expired, but at various times there's been uncertainty about whether the first filer also had to successfully defend in the patent litigation. At certain times the FDA has required it to not only be the first filer, but you also successfully defend in a patent litigation.

If that held true, Upsher-Smith, having settled with Schering and their patent litigation having been dismissed, didn't successfully defend and might not have the 180-day exclusivity period. If it didn't, Upsher wouldn't be blocking ESI. So, that ESI threat was an incentive to Schering to come to some

accommodation with ESI as well.

Schering and ESI negotiated their agreement over a several-month period. Initially, ESI offered to pay royalties for a license to Schering's patent. Schering rejected that offer and made a counter-offer that if ESI would abandon their application for the generic, Schering would permit ESI to co-promote the branded K-Dur 20 product. ESI turned down that counter-offer.

Later, ESI offered that it would delay entry of its generic, but it wanted to be compensated for the revenues it would lose by delay. Schering and ESI agreed that Schering would pay ESI $5 million initially and up to another $10 million depending on when and if ESI received tentative approval from the Food and Drug Administration for its product. In exchange, ESI agreed not to market its generic until January 2004.

ESI also agreed that it would market only one generic between January 2004 and when Schering's patent would expire in September 2006, and ESI agreed that it wouldn't file an application for another generic K-Dur 20 or support any other company's application. ESI received tentative approval quickly enough that it got the full $10 million from Schering.

Why are these agreements unlawful? Because

Schering's agreements delayed competition and harmed consumers through forcing them to pay higher prices. The evidence will show that the agreements were illegal because they were a market division among competitors. By agreeing to delay entry, the companies divided the market, reserving all of it to Schering for a period of time and only then allowing later the generics to come in and compete for a portion of the market. The delay harmed consumers by forcing them to continue paying a higher branded product price. It's undisputed here that if there was delay, every day of delay harmed consumers. The central issue is whether the payments were for delay. The evidence will show that the agreements, in fact, were for delay.

Professor Bresnahan, professor of economics at Stanford University, will explain what our common sense suggests. Schering didn't pay $60 million for nothing. At the time of the agreement, Schering faced two choices, either litigate or settle. If Schering thought that by litigating it was likely to get a better outcome than generic entry in September 2001, it would make no sense for Schering to pay Upsher-Smith $60 million to get this thing resolved.

If Schering thought that Upsher would settle for a September 2001 entry date without the $60

million, it would, again, make no sense for Schering to pay Upsher that amount of money. The $60 million payment only makes sense if Schering thought it would get a later entry date, a longer period free from generic competition and a longer period with greater sales volume than it would have if it litigated the case or settled without payment.

The parties' experts will present theories in an effort to obscure these plain facts, but as Professor Bresnahan will explain and other evidence will show, none of respondents' experts' theories is borne out by the facts of the case. Schering didn't pay millions of dollars to Upsher because Upsher needed money. Schering didn't pay millions of dollars to ESI because ESI's parent, American Home Products, was judgment-proof. It paid for the simple reason that it was worth millions of dollars to Schering to keep the generics off the market.

As Professor Bresnahan will explain, these facts provide a basis for finding not only a horizontal market division, but also monopolization by Schering and a conspiracy to monopolize between Schering and Upsher and Schering and ESI. Professor Bresnahan will testify that the market effect caused by actual generic entry once it arrived, together with other evidence,

shows that Schering had monopoly power in the United States for 20 milliequivalent potassium chloride tablets and capsules.

Upsher and ESI posed a direct threat to that monopoly, but as seen earlier, Upsher and ESI when they entered would not capture all the revenues that Schering would lose. Some of those lost revenues would be savings to consumers. So, there was an incentive for these three companies to extend the period of monopoly profits and then divide those profits among themselves. As the evidence will show, that's exactly what they did.

Respondents say that the payment to Upsher was not for its agreement to delay, but rather, for a license of Niacor-SR. Niacor-SR was a sustained release niacin product that Upsher-Smith was working on in 1997. The argument that the payment was for the license flies squarely in the face of the evidence. The evidence will prove that the $60 million was not for the license.

First, the $60 million noncontingent payment for a license was the largest noncontingent payment Schering had made up to that time. Second, Schering did only five days of due diligence on the Niacor-SR instead of the months it normally spent examining a

potential licensed product. Third, Schering's conduct after the agreement was signed doesn't demonstrate a desire to market the licensed product. Fourth, about the same time Schering entered into the Niacor license with Upsher, Schering turned down a license on a similar but superior product. Fifth, Upsher offered a license on Niacor-SR to over 40 companies, and not one offered as much as $1 in noncontingent payment.

You will hear from Dr. Levy, who has held senior positions in two multinational pharmaceutical companies and consulted for or served on boards of numerous pharmaceutical companies, that in his opinion, the $60 million payment was not for the license of Niacor-SR. How does Dr. Levy know this? From the evidence.

First, this $60 million noncontingent payment is the largest noncontingent payment Schering had made up to that time. Drug companies rarely pay enormous amounts of cash with no strings attached and no protection for their investment. Royalties have a built-in protection, because they're paid only upon actual sales. Payments linked to milestones have built-in protections, because they depend on the occurrence of certain events in development or regulatory approval of a product. Payments for an

equity position in the licensor have built-in protection, because even if a single licensed product fails, the licensor may come up with other products that will succeed.

But Schering's payment to Upsher had none of those protections. It wasn't linked to sales, it wasn't linked to occurrence of any milestones, and it was not protected by gaining any equity in Upsher. Schering owed the full $60 million even if Upsher did no further work on Niacor. Upsher could completely drop the ball on development of Niacor-SR, and Schering would still be obliged to make the full payment so long as Upsher didn't launch its generic before September 2001.

In fact, within a few months of the signing of this agreement, Niacor proved to have no future, as sometimes happens with drugs that are under development, but Schering kept on paying, because it was getting something in return for its $60 million. It was getting Upsher's commitment not to enter the market.

Second, Schering didn't perform anything like the normal due diligence that Schering or other pharmaceutical companies would perform before paying $60 million for a proposed licensed product. All

Schering did was an abbreviated assessment which would normally be just the start of due diligence. That assessment was done by two people over a matter of a few days. Normally, Schering has a multidisciplinary team that analyzes a potential license over several months.

With Niacor, Schering ignored several parts of due diligence. Schering did not examine the patents pertaining to Niacor. Schering did not analyze the regulatory status of Niacor, didn't ask for access to files of communications between Upsher-Smith and the FDA about Niacor. Schering did not have its scientists review clinical data for the safety and efficacy of the product. Schering did not confer with the managers of its European subsidiaries who were going to be responsible for selling this licensed product.

In fact, some of those managers had rejected a license of Niacor-SR a few months before the June '97 agreement. Schering did not do a manufacturing review to determine if Upsher-Smith was capable of manufacturing Niacor, although the agreement gave Schering the option of purchasing Niacor from Upsher.

The exhibits from Schering's and Upsher's files will show that Schering's conduct after the agreement was entered into is inconsistent with the license --

I'm sorry, with the payment being for the license. The time frame presented to Schering's board for development and marketing of Niacor-SR would have required that the company immediately mount an enormous effort to get the product approved and to be ready to manufacture and market. The evidence shows no such effort was made.

The evidence will also show that Schering turned down a license for a superior sustained release niacin product about the time it entered into the license with Upsher. Schering was negotiating with Kos Pharmaceuticals, Incorporated that was developing a sustained release niacin product, but Kos' product was superior to Upsher's in several respects.

First, Kos' product was closer to FDA approval. Second, Kos' product had a better side effect profile. And third, Kos' product needed to be taken only once a day, whereas Upsher's product would have to be taken twice a day, and patients tend to comply with the physician's instruction and take the pills they need if they have to take them only once a day rather than multiple times. Yet Schering offered no up-front payments to Kos and broke off the license negotiations in June of 1997.

On Upsher's offer of the Niacor license to

other pharmaceutical companies, Upsher made an offer of the license to over 40 companies. Ten of them never even responded; 24 turned down the license without giving any specific reason; 11 of them turned down the license because of either side effects or the lack of sales potential. Only five companies even had an initial meeting with Upsher, and not one of them offered any money noncontingent for a license to Niacor.

Respondents also argue that there's a public policy in favor of settlements and that parties should be able to resolve their patent litigation without having to prosecute the case all the way to a court decision. Complaint counsel don't disagree that there can be benefits to the public as well as to the private parties from a patent settlement. We're not saying that parties cannot settle. We're not saying that parties cannot settle even with delayed entry as long as there's no payment, because if there's no payment, the generic has an incentive to come to market as soon as possible, which is also in the interests of consumers, but once the payment is introduced, that changes the incentive.

What we're saying is the patent holder may not pay the generic company, the alleged infringer,

resulting in a delayed entry date to the detriment of consumers. We're saying there must be no reverse payment for delay. It's not necessary to litigate the merits of the underlying patent litigation, but the Court can decide that these agreements are anti-competitive even without deciding who would have won the patent cases. Absent the payments, the generics would have settled only for an earlier entry date or continued litigation to a court decision.

Now, earlier entry would clearly have benefitted consumers. If the parties had continued their litigation, there was some uncertainty about who would win, but consumers are better off with the possibility of earlier generic entry than with a date agreed to by competitors in the presence of a payment.

Moreover, we can never replicate that patent litigation. We can never know how the courts to which those cases were assigned would have decided the outcome. That's particularly true as here, where the generic companies, Upsher-Smith and ESI, no longer have an incentive to vigorously prosecute their position in the patent litigation.

Where's the proof of the pudding? The proof of the benefit to the parties and the harm to consumers caused by the agreements can be seen in what has

happened since September 1st, 2001. That's the date on which Upsher's generic finally came to market as permitted by the terms of the agreement. Upsher has priced its product almost 50 percent below K-Dur 20's price.

This illustration shows what has happened to the number of prescriptions dispensed. This isn't measured in dollars but number of prescriptions dispensed. We see that in the first month, generics, which would include Upsher and Schering's own generic, generics in that first month gained 20 percent of the prescriptions for 20 milliequivalent potassium chloride tablets. By the second month, generics already had 50 percent of the prescriptions. And by the third month, the generics had 60 percent. These numbers will only get better for consumers and worse for Schering.

The majority of consumers are now paying half the price for the 20 milliequivalent potassium chloride tablets that they were paying before September of last year. Before then, consumers with high blood pressure were footing the bill for an arrangement that let Schering continue to charge monopoly prices and the competitors to pocket the profits.

I have not addressed all the factual issues here. The evidence that will come in over the course

of the trial will provide much more richness of detail. There will be a multitude of documents as well as testimony contemporaneous with the conduct that will prove Schering's payments to Upsher and ESI were for the purpose of delaying generic entry.

I urge Your Honor after the close of the record, as you're sifting through the evidence, to accord more weight to contemporaneous evidence than to documents, testimony or legal argument prepared after the parties learned of the Federal Trade Commission investigation.

By entering into the agreements, Schering protected its revenues and reaped millions of dollars in profits, some of which it gladly shared with Upsher-Smith and ESI. Schering, Upsher and ESI were the winners. Consumers, who continued to pay high prices, were the losers.

At the conclusion of the trial, we will ask Your Honor to conclude as a matter of law that Schering's agreements with Upsher and ESI unreasonably restrained competition, and Schering monopolized the 20 milliequivalent potassium chloride tablet supplement market and that Schering and Upsher and Schering and ESI conspired to monopolize the relevant markets in violation of Section 5 of the Federal Trade Commission

Act.

Thank you for your attention.

JUDGE CHAPPELL: Thank you, Ms. Bokat. Also, Ms. Bokat, who is the witness the Government intends to call today, the name?

MS. BOKAT: His name is Dean Goldberg from United Healthcare Group.

JUDGE CHAPPELL: And is he available in town?

MS. BOKAT: Yes, sir, he is.

JUDGE CHAPPELL: Thank you.

Does Schering-Plough wish to make an opening statement at this time?

MR. NIELDS: Yes, Your Honor, I do -- we do. It would be helpful to have about a minute and a half to set up, if that would be permissible.

JUDGE CHAPPELL: That's fine. We're all here. Just let me know when you're ready.

(Pause in the proceedings.)

JUDGE CHAPPELL: Mr. Nields, you may proceed.

MR. NIELDS: Just even before I begin, Your Honor, there is a chart which has been put up which depicts the settlement with Upsher. Ms. Bokat has just had a chart showing that at the present time, Upsher's product is on the market and is selling at low prices. That, Your Honor, is because of the settlement

agreement. Absent this settlement agreement, Schering may well win the litigation, Upsher's product doesn't get on the market until 2006. Because of the settlement agreement, Upsher is on the market today. According to complaint counsel, that is pro-competitive, and it is pro-competitive.

Your Honor, we will be calling our witnesses live. We will call the witnesses who participated in the negotiation of both settlement agreements. We will call the witnesses who evaluated the Niacor product, and we will call the witnesses who evaluated the Kos sustained release niacin product, Niaspan. They will all be here, Your Honor, and will testify live.

One of the witnesses that we will call is a man named John Hoffman. Mr. Hoffman, Your Honor, is a lawyer in-house at Schering-Plough. He is in charge of litigation, and he is also in charge of antitrust. Mr. Hoffman, Your Honor, was the lawyer responsible for these settlement negotiations, and as I've already mentioned, by background and training, he is an antitrust lawyer. He practiced at a large firm in New York up until two years before these settlement agreements when he joined Schering-Plough, and we think, Your Honor, after you have heard him, you will conclude that he is a good antitrust lawyer.

Complaint counsel put up a document on the screen earlier entitled Executive Summary, which she quoted from, but she left off one part of the document, and it's in small -- the whole document is hard to read, so why don't I read it to you. It says, Your Honor, that, "Goals for the Upsher-Smith settlement: 3, any agreement must pass all legal and regulatory constraints, e.g., FTC."

Now, Your Honor, at that time, the law did not provide any clear rules applicable to a settlement of an intellectual property dispute. Indeed, this is still a case of first impression today, it certainly was then, but Mr. Hoffman, in his discussions with Upsher-Smith and ESI, laid down very clearly the rules that would govern any settlement that Schering would enter into. He told them Schering would not pay for them to stay off the market. He told them that Schering would negotiate a settlement in which the parties set an entry date by agreement earlier than the date on which the patent expired, that that date would be set by the parties agreeing on what was appropriate given the strength of each of their cases. And he also said that Schering would consider transactions of mutual benefit, unrelated to the matters in dispute, so long as -- and these are his words in a deposition --

such a transaction "stood on its own two feet." In other words, so long as if Schering was paying for something, they got fair value in return.

Your Honor, complaint counsel agrees with Mr. Hoffman's rules. They said so in their trial brief. This is a quote from page 43 of their trial brief, and taking the first clause, complaint counsel says, "This case does not challenge the settlement of patent disputes by an agreement on a date of entry, standing alone." So, they agree with Mr. Hoffman's first principle, the parties can settle a patent dispute by agreeing on a date of entry earlier than patent expiration.

Then complaint counsel goes on, "or the payment of fair market value in connection with 'side deals' to such an agreement." So long as the transaction of mutual benefit is for fair value, complaint counsel agrees that is appropriate.

Now, Your Honor, in suggesting that Schering would consider a transaction of mutual benefit unrelated to the matters in dispute, Mr. Hoffman was pursuing a widely recommended and common method of trying to settle any kind of litigation. We will call as witnesses here, Your Honor, experts in mediation and negotiation, experts in settlement of legal disputes.

One of them will be Professor Robert Mnookin, who is a professor at Harvard Law School, and he's in charge of their project on negotiations. He has written books about this, Your Honor, and he recommends in his books and in his courses that people trying to settle a dispute, they should affirmatively look for transactions outside of the matter in dispute that will be of mutual benefit to the parties, and that if they do that, it will be easier to settle the matter in dispute. And that's the way the Upsher case was settled.

Your Honor, the ESI case was actually settled pursuant to court-supervised mediation, and it was settled in a similar fashion. The parties agreed on a date of entry earlier than patent expiration. They did a license agreement for fair value, and in that case, a small amount of cash in addition was paid by Schering to ESI at the express urging of the United States Magistrate Judge that was supervising the negotiations, and it was done with his full knowledge and approval after Schering had explained the antitrust issues to him.

Your Honor, we believe, as we've said in our trial brief, that this case will be governed by the rule of reason, and we plan to introduce evidence that

both settlements were reasonable and neither one of them was anti-competitive. As to the ESI settlement, we will prove that it had the approval of the United States Magistrate Judge, that there was no proof of payment for delay, and that the settlement yielded more competition than litigation would have.

As to the Upsher settlement, we plan to prove that Schering paid fair value for Niacor. We plan to prove that there is no proof of payment for delay, and we plan to prove that the settlement yielded as much competition as the litigation would have. I would like to outline that proof for Your Honor now, if I may.

I'm going to treat the ESI case first, and we plan to present proof on that case first so that when we then put in the Upsher proof, it will be consecutive to the proof put in by Upsher, who is the only remaining party in this case.

As I've already said, Your Honor, the ESI case was settled as a result of court-supervised mediation.

JUDGE CHAPPELL: I'm sorry to interrupt you, Mr. Nields, but in your order of presentation, do you know that Upsher-Smith's attorney is going to do the same thing, just for my purposes?

MR. NIELDS: Well, Upsher -- they will only present evidence on the Upsher case, because that's the

only one that affects them.

JUDGE CHAPPELL: But are they -- are they aware -- they are not learning for the first time right now your plan?

MR. NIELDS: No, they are not.

JUDGE CHAPPELL: Thank you.

MR. CURRAN: That's right, Mr. Nields was kind enough to confer with me on that, and I'm in full agreement with that order of presentation.

JUDGE CHAPPELL: Thank you. Proceed.

MR. NIELDS: Your Honor, the ESI litigation was settled as a result of court-supervised mediation. The U.S. District Judge assigned to the case appointed United States Magistrate Judge Thomas Reuter to supervise the settlement proceedings, and he conducted, Your Honor, five separate formal mediation proceedings either in his courtroom or in his chambers over a period of about 15 months.

Early, Your Honor, in those negotiations, ESI suggested to Judge Reuter that Schering pay $90 million and they would agree to stay off the market for some period of time. That was passed on to Schering by Judge Reuter, and Schering said they would not do that, and Schering gave two reasons. The first one was that Schering had a very, very strong case, and there was no

reason to enter into any such settlement for that reason. Second, Schering told Judge Reuter that Schering had antitrust concerns about any such settlement.

This issue came up several times during the mediation, and Schering, every time it came up, made the same two points. Our case is very strong, we're going to win it if we go to trial, and payments raise antitrust issues.

Indeed, Your Honor, Schering made no real offer in compromise of that litigation until 13 months into the mediation. Your Honor could find, and I believe will find, from the evidence that absent Judge Reuter's involvement, there would not have been a settlement. The case would have been tried, and Schering would have won it.

But Judge Reuter strongly and repeatedly urged Schering to settle the case, and in December of 1997, Schering made an offer of settlement, and the offer, Your Honor, was to agree on a date of entry which was the date finally agreed upon, the beginning of the year 2004, and Schering also agreed to discuss licensing of products from ESI if they had products that were worth licensing. ESI accepted the date of entry fairly soon after that offer, and the parties were then negotiating

over the licensing.

On January 23rd, Your Honor, the parties had their final mediation session with Judge Reuter. The date had already been agreed on. The parties were discussing the license. Schering agreed to pay $15 million for the license, no more. ESI didn't want to settle. Judge Reuter strongly leaned on Schering to make a payment that he characterized in the neighborhood of legal fees --

JUDGE CHAPPELL: Wait, that was $15 million for the license of what?

MR. NIELDS: It was a license of two generic products, enalapril and buspirone, Your Honor, and complaint counsel, I believe I can say with confidence, is not going to quarrel that that was fair value. They have no evidence that it wasn't, and we have plenty of evidence that it was, but Schering was not willing to pay more.

Complaint counsel described Schering as a company that just wants to disguise payments inside of a licensing agreement. The evidence will show the opposite. Schering said we're paying $15 million, no more, for those licenses. Judge Reuter said he wanted Schering to pay some additional amount in the neighborhood of legal fees in order to get the case

settled. Schering agreed to do so. The settlement agreement was reduced to writing in Judge Reuter's chambers. He had full knowledge of every element of that agreement. He gave his full approval to it. It was signed in his presence, Your Honor, and that was the agreement in principle.

Six months later, Schering and ESI finally entered into a more thorough, typewritten agreement, but the agreement was entered into in principle, and we have that agreement, and we will introduce it into evidence, in Judge Reuter's chambers subject to his full approval after the antitrust issues had been explained.

Then, Your Honor, three days later, the District Judge sent the parties a letter -- I'm sorry, Your Honor, these are technical issues that --

JUDGE CHAPPELL: I believe you touch an icon that looks like the ELMO.

MR. NIELDS: The icons aren't up there. Thank you.

-- the first paragraph of which congratulates the parties on getting the case settled and points out that the settlement -- the resolution of the dispute accommodated the interests of the parties but which could not have been awarded by the Court at trial,

because it was a compromise, and the Court congratulates them for a job well done.

Your Honor, the witnesses that will testify about the ESI negotiations are now listed on the screen in front of Your Honor. Tony Herman, Your Honor, is a -- was Schering's principal outside counsel. He is a partner at Covington & Burling, and he was present for every one of the mediation sessions, and he is in a position, Your Honor, to describe the full scope from beginning to end of the mediation process that Judge Reuter conducted.

He will describe the conversations they had on offers and counter-offers, on discussion of antitrust issues, and he will tell you that right before the very last session, the District Judge had ordered the parties on a Friday -- late Friday afternoon to go to Judge Reuter's chambers and not to leave until they had settled the case.

Charles F. "Rick" Rule, Your Honor, is another partner at Covington & Burling -- he was then, he is now at a different firm -- and he will testify as to the conversations that he had with Judge Reuter. Mr. Rule, Your Honor, had previously been the Assistant Attorney General at the Justice Department in charge of antitrust, and he will testify that he went at

Schering's request to explain the antitrust issues raised by a settlement which included a payment.

He will recount that Judge Reuter told him how can there be a problem if I am approving such a settlement? And Mr. Rule told him that would help, particularly under the rule of reason, but it's not an absolute blessing. It's not an absolute immunity. He also explained to Judge Reuter that a payment in the nature of legal fees would be all right and that if a payment had to happen, the one thing it should not be is a payment calculated out of Schering's profits. And, of course, that was not what eventually happened.

Mr. Kapur, Your Honor, was head of Schering's generic subsidiary. He will testify to the conversations that he had on the subject of the license for the two generic products, enalapril and buspirone.

Mr. Driscoll, Your Honor, was a Schering executive who was responsible for this lawsuit, was responsible for the product. He will testify to conversations that he had and was present for with Judge Reuter, the final one being on January 23rd, the date the agreement was struck, only those conversations occurred when he was at a New Jersey Nets game with his son late on Friday evening, and he received several calls on his cell phone from Judge Reuter and, indeed,

at one time was told by Judge Reuter that if a settlement wasn't concluded that evening, Mr. Driscoll would have to come to court the following morning on Saturday and meet with the District Judge in charge of the case.

Your Honor, going back to the chart on the right, settlements were reasonable, ESI settlement, the evidence will conclusively show that this settlement had the approval of Judge Reuter, and the evidence will also show that there is no payment for delay. The date of entry had been agreed upon by the parties first. Then the parties talked about the license and the other financial provisions.

Finally, Your Honor, we will introduce evidence that the settlement yields more competition than litigation, and that brings me to the patent case, because the litigation was about the patent case. I had intended to do this sooner, Your Honor. I've put a K-Dur pill in a glass of water, and what will happen in the course of the next few minutes is that pill will or capsule -- tablet, excuse me, will disintegrate, and what's in there are many, many, many, many, many crystals, potassium chloride crystals, and each one of those, each crystal is coated. It's coated with a material that produces the sustained release effect.

The potassium chloride capsules leach through the coating, and because of the particular kind of coating, it leaches through slowly, so that the potassium chloride goes into the person's system in a gradual and continuous way over an extended period of time.

JUDGE CHAPPELL: So, for the record, you have a glass half full of water with a white tablet in it.

MR. NIELDS: Yes, Your Honor, although soon it will not be tablet. You can see it starting to -- the crystals starting to float up, many, many, many crystals.

Schering was by no means the only company, Your Honor, that had figured out a way of putting potassium chloride and coating it and making it an extended release or sustained release product. Others had done that before. What nobody had been able to do before was make a coating material that could withstand the pressure that is required to put a 20 milliequivalent dose in one tablet. So, there were other extended release 10 milliequivalent potassium chloride products on the market. Schering was the only one who figured out a way of doing an extended release mechanism coating that would withstand the pressure that was necessary to make a 20 milliequivalent dosage.

The issue in the ESI patent case, Your Honor, obviously was whether ESI's method infringed Schering's patent. It used essentially the same ingredients to coat the same crystals. It argued that it had a -- that it was different, though, because there were two important ingredients, and they claimed Schering's were mixed together and that they applied theirs in two separate coatings. That was basically their defense, that they put on two ingredients, first one coat then another, not mixed.

Well, Schering hired a world renowned scientist who subjected ESI's product to scientific tests that showed that, in fact, those two ingredients were mixed, and that pretty much torpedoed ESI's defense, and you will hear testimony to that effect, Your Honor, and you will hear testimony that if the case had been tried, Schering would have won. And if they had, ESI would have been off the market until the year 2006, September of 2006. Under the agreement, ESI was permitted to enter the market 32 months earlier than that. That is a pro-competitive settlement. What Judge Reuter, Your Honor, at the end of the day engineered was a pro-competitive settlement.

Your Honor, that brings me to the Upsher settlement agreement. In the Upsher case, Your Honor,

the negotiations began about a month before the trial date. Again, early on, Upsher requested that Schering make a payment in return for which they would agree to stay off the market. Schering again made it very clear that they would not do that. Again, Schering indicated they would discuss a settlement built around the idea of an earlier entry date, an entry date earlier than the patent expiration date, based upon the parties' respective strengths in the underlying patent litigation, and Schering also indicated that it would be willing to pursue transactions of mutual benefit so long as they stood on their own two feet. And again, Your Honor, you will hear testimony from negotiation and mediation experts that this is a common method for trying to settle a lawsuit.

First, the parties settled on a September 1, 2001 entry date. That was the first thing they did. Parallel to that, they were discussing various possible license agreements whereby Upsher would license products to Schering and Schering would pay them. For a while, all Upsher put on the table were some generic products. Upsher is, generally speaking, a generic manufacturer and pharmaceutical company, and they talked about various generic products with Mr. Kapur. None of them, however, was worth an awful lot of money

to Schering.

Then, on June 12th, 1997, six days before the trial was to begin, Upsher came to a meeting at Schering with a packet of material on a product called Niacor-SR. You will hear lots of testimony in this case, Your Honor, about this packet of material. This is what it was. It described clinical trials, it described lots of other information about Upsher's product. It was far along in development. I mentioned these generic products that Schering didn't think would produce much value. Niacor-SR was a horse of a different color.

First of all, it was a brand name product. It was not a generic. It was a product that Upsher had developed and invested many millions of dollars in development. Second, Your Honor, Schering had -- oh, by the way, the offer on Niacor was for the rights to market Niacor outside of the U.S., Canada and Mexico. Schering two months earlier had evaluated another sustained release niacin product for the U.S. market and after a long period of evaluation had concluded that that product would throw off profits of $254 million. That product, Your Honor, was evaluated by a Schering employee named Ray Russo, and he will testify in this courtroom.

Your Honor, Mr. Russo made sales projections for this product which was called Niaspan, and it's the product that was owned and developed by Kos, and he in his projections showed that it would develop sales very soon of over $100 million a year going up nearly to $200 million a year.

Your Honor, this is very important. Nobody, not complaint counsel, not anybody, quarrels with the good faith of Mr. Russo's projections for Niaspan. This didn't have anything to do with any settlement agreement. This represented, in complaint counsel's submission, nothing other than Mr. Russo's best good faith judgment about how successful that product would be, and as I've already said, if you translate those -- and it's easy to do and Schering did it at the time -- with contemporaneous documents, Schering concluded that those sales would throw off profits of $254 million with a present value of $254 million. So, when Upsher came in with its Niacor product, a sustained release niacin product for sales overseas, Schering thought this might be a real opportunity.

Now, Mr. Kapur, who was there when this packet was delivered, was a generic -- he was head of their generic company. He was not qualified to evaluate Niacor. So, he gave this packet to Thomas Lauda, who

was the head of Schering's global market division, and Mr. Lauda gave it to Mr. Audibert, who I will describe in a moment, for an evaluation, and this gets to what is likely to be one of the most important issues in this trial, so I'm going to take just a moment to describe this product that Mr. Audibert was assessing.

Niacin, Your Honor, is an old drug. Its properties are very well known. It is very good at reducing cholesterol, bad cholesterol, and it's very good at elevating good cholesterol. There's tons of literature on that. Everybody knows that. Mr. Audibert knew that. The problem is it causes a bad side effect, which is flushing, not a health risk, but it's very unpleasant, and so people just wouldn't take normal niacin, immediate release niacin as they call it.

And what Upsher had done, just as what Kos had done, is they had taken niacin and put it in a sustained release form, retaining the effectiveness of the drug but diminishing the side effects significantly, okay? So, that's the product that was put in front of Mr. Audibert with this packet of clinical trial summaries and so forth.

Your Honor, Mr. Audibert, the evidence will show, was superbly qualified to evaluate this product.

He is a scientist by training. He holds a Master's in pharmacology. He had been in the research and development department of another drug company before he came to Schering, and indeed, he's in the research and development department of Schering today. He had designed clinical trials, many of them, he had supervised clinical trials, he had monitored clinical trials, he had been reading results of clinical trials throughout his professional career. He was Schering's resident expert on cholesterol-reducing drugs.

Partly -- he was head of the cardiovascular part of global marketing, but he had recently been focusing on cholesterol-reducing drugs, because Schering's most important product in the pipeline then and still today is a product called ezetimibe for cholesterol reducing, and he had learned the market in the U.S., he had learned the market overseas, he knew every drug that was out there for treatment of cholesterol and many that were in development, he knew their advantages, their disadvantages and their side effects.

He had also had extensive experience in sustained release technology. He had been responsible for several old drugs that Schering and its predecessor Key had developed by using sustained release technology

and turning an almost nothing drug into a drug that sold over $100 million a year. He had extensive experience with that kind of drug. And he also knew the overseas markets, because he was in global marketing. That's what global marketing, Your Honor, did at Schering. So, he reviewed these materials, and he came up with his sales projections.

I've now put up on the board Mr. Audibert's sales projections for Niacor, and once again, Your Honor, this is a very important document that the Court is now looking at, because if this document is accurate or if this document represents Schering's best judgment at the time about the sales that Niacor was likely to get overseas, then complaint counsel doesn't have a case. They are not arguing that Mr. Audibert made a mistake in business judgment. They are arguing that Schering deliberately overvalued Niacor. They're arguing that it was a sham transaction, in effect.

If you take these numbers, Your Honor, it's a simple question of math to find out that they throw off a profit of $225 to $265 million. That math was done for the board of directors when the board of directors approved this license agreement.

And Your Honor, here is a point I would again like to emphasize. It seems inconceivable to us that

complaint counsel is going to be able to show that this was not Mr. Audibert's best good faith projections of the sales for Niacor overseas when they are very much in the same range as Mr. Russo's projections for Niaspan.

Now, I've put one on top of the other, and you can see the years don't match exactly and the numbers don't match exactly either. The Niaspan numbers in the U.S. look a little better than the Niacor numbers overseas, but they are very much in the same range. And, Your Honor, we will present expert testimony that in 1997, the cholesterol -- the market for cholesterol-reducing drugs outside the United States was a little bit larger than the cholesterol-reducing market in the United States.

We will also call, Your Honor, our own expert in the valuation of pharmaceutical products, and he will testify that he believes Mr. Audibert's projections were accurate, reasonable, and so were all of the underlying assumptions upon which they were made.

Now, Your Honor, complaint counsel has quarrelled with the due diligence. They say somebody should have taken a look at the patents. But you will see when this document gets introduced in evidence at

trial, Mr. Audibert assumed that there -- that the Upsher patent would not block competitors overseas. He just assumed that away. He made these projections on the assumption that there would be other companies that would come into the market and compete with Niacor.

She said nobody looked at the regulatory status. Well, that is frequently not done, even on drugs that are way more complex and difficult to understand than a sustained release version of an old, known drug.

She says no scientist reviewed it. Well, excuse me, Your Honor, we will prove that Mr. Audibert is a scientist, and indeed, it is very unlikely there was anyone at Schering as qualified to make this analysis as he was.

She said that nobody consulted the managers in Europe. You will hear lots of testimony, Your Honor, that that is the exception rather than the rule when you've got a product like this that you're going to be marketing for outside the United States, to go ask all of the different managers in all of the different countries. Mr. Lauda was in charge of global marketing. He will give that testimony.

Now, the one remaining issue, Your Honor, I think we would all agree that if Schering had marketed

this product and earned this money, we wouldn't be here. We are here because Schering decided not to. So, the question then is why, and there's an answer, Your Honor.

There was an event that occurred a couple of months after Schering signed this agreement and long before it would have actually marketed the product or even long before it would have submitted the regulatory packages to the agencies that would approve. What happened was this: Kos' product hit the marketplace in the U.S. in August of 1997, and it bombed. It bombed, Your Honor. The product that Schering thought was going to be selling $100 million a year in a few years just bombed.

What I've done here, Your Honor, is I've put up a chart that shows Kos' stock price over time. Kos was essentially a one-product company, Niaspan, a sustained release niacin product. It launched its Niaspan product in mid-August 1997, and you'll see just a little bit later than that, the IMS data, the sales data started hitting the press, and that line that goes straight down is what happened to their stock price once their disappointing sales came in. You can see that the stock price was at 44, and after the product got launched, it dropped down to about 5. Schering saw

those, Upsher saw those and concluded that this product wasn't what they had thought that it was, and they decided not to invest any more money in it.

Your Honor, I have now put up a chart of the witnesses that will testify on the Upsher agreement. On the left-hand side, Your Honor, are two -- the two officials who will testify about the negotiations with Kos, Mr. Russo and Mr. Driscoll. Mr. Russo will testify, of course, about his evaluation of Niaspan and how much he thought it was worth, and so will Mr. Driscoll. They will both testify, Your Honor, about the negotiations and the reason why no deal was eventually struck.

Ms. Bokat keeps referring to the fact that Schering didn't do a license with Kos. Well, the discussions between Kos and Schering were not about a license. They were about a joint venture. That's different. With Niacor, Schering was buying the rights to market Niacor overseas. The Kos discussions were about a joint venture in which Kos would contribute the product and Schering would contribute its sales and marketing muscle and expertise. They were each putting something in.

The negotiations were about how the profits would be split, who would be in control of the strategy

and things of that nature, and you will hear testimony that Kos had a very exaggerated idea about how much its product was worth and therefore how much it should get as compared to Schering, and you will hear that the discussions between the parties were not comfortable, and it was quite clear to Schering that Kos was going to be a very difficult partner. Schering eventually decided not to do the deal with them after they had made a very serious offer in writing, which the Court will see.

The evidence will show, as I've already indicated, that right up to the end, Schering never waivered from its prediction that this product would spin off $254 million in products.

Next, Your Honor, there are a number of witnesses who would testify about the actual negotiations. I think I've already summarized that. And then, Your Honor, there is Mr. Audibert, whose testimony will be very important, and Mr. Lauda as well, who was head of global marketing. Mr. Lauda will also be able to give some testimony about how Schering goes about in-licensing products, and it will become important, I believe, or at least relevant to learn from Mr. Lauda that Schering frequently, indeed most of the time, when it evaluates a product for in-licensing,

it has no idea whether there are any other companies bidding for that product, and if there are, what they're bidding.

What Schering does virtually invariably is exactly what it did here. Schering does its own valuation. It comes up with its own decisions about how much the product is worth and then negotiates for the best deal that it can get. Indeed, Mr. Lauda will tell you about one product, Your Honor, where Schering made a $30 million up-front payment and a commitment to do way over $100 million in clinical research at a time when they knew to a certainty that the company selling them the product had no other bidders, nobody else was interested, only Schering, and was a product that the FDA had twice turned down.

So, getting back to my chart, Your Honor, the evidence will show that Schering paid fair value for the Niacor license, and it will certainly show that they paid way less than their own business judgment told them it was worth.

Second, the evidence will show that there is no proof of payment for delay. Once again, the parties first settled on the entry date, then they went and bargained over Niacor.

Third, Your Honor, we will introduce once again

evidence about the patent case that will support the proposition that the September 1, 2001 entry date is just about exactly where you would expect it should be given the strength of each of the parties' cases.

Your Honor, I'd like to address just a couple of issues more, and then I will be through. One of them is this question of monopoly power. It is true that K-Dur was the only potassium chloride extended release product on the market that was in a 20 milliequivalent dosage form, and it is true that that was a good thing for Schering, and Schering marketed that sort of compliance advantage, but Your Honor, there were many 10 milliequivalent extended release potassium chloride products on the market, and what that meant was that although Schering had a 20 milliequivalent pill, which I think Ms. Bokat has already shown you, it's a big pill -- I'm not going to take this one out, but it's a good size pill --

JUDGE CHAPPELL: And for the record, the one you're holding is what size?

MR. NIELDS: Twenty milliequivalent.

JUDGE CHAPPELL: That's a K-Dur?

MR. NIELDS: This is the K-Dur, but there were many other products, Your Honor, that were 10 milliequivalent. This is called K-Tab. In order to

get a 20 milliequivalent dosage, you would have to take two pills.

JUDGE CHAPPELL: For the record, you are holding the 10 milliequivalent now?

MR. NIELDS: I am holding two pills, each of which is a 10 milliequivalent pill.

JUDGE CHAPPELL: Are those capsules or tablets?

MR. NIELDS: These are tablets, just like K-Dur, tablets.

So, Schering may have had an advantage, Your Honor, but it's hardly the case that it had no competition. If someone wanted a low-priced dosage, one could go buy a bottle of low-priced 10 milliequivalent pills, take two of them.

I've put up a chart now, Your Honor, of -- these aren't all the products on the market, but these are several of them, and they show the prices by dosage. In other words, these aren't prices of the pills; they're prices of a 20 milliequivalent dosage. So, it's in effect the price of the two 10 milliequivalent pills as compared to the price of one 20 K-Dur pill.

If you look, for example, at 1997, you will see two things. First of all, you will see that Schering is not charging the highest price in spite of the fact

that Ms. Bokat thinks we're -- we were a monopolist then. We're not charging the highest price. And the second thing you will see is that there was plenty of low-priced competition. Indeed, the one at the bottom, ethex, is a generic. It's just a generic of a 10 milliequivalent product.

Now, the economists will come in here, Your Honor, and they will testify about monopoly power and various things like that. We will have ours and they will have theirs, and the Court will have to listen to them and decide who is more persuasive. I just wanted to give you this kind of brief introduction, because it seems to us it is far from obvious that Schering had monopoly power just because it had the only 20 milliequivalent dosage product.

Your Honor, another issue that's going to come up is the issue that we've argued before as lawyers in the motion to dismiss, and Ms. Bokat mentioned it again today, and that's this question of the 180-day exclusivity and whether Upsher had those rights, whether it has them now and so forth, and there will be expert testimony on the subject of the 180-day exclusivity rules that the first generic filer gets.

For the purpose of this trial, however, Your Honor, we think there's really only going to be one

crucial issue, and it's the one that Your Honor told us about in Your Honor's opinion, and what you told us is what we have to try, and that's the question of whether there was a concerted agreement between Schering and Upsher to manipulate the start date of the 180-day exclusivity period.

Your Honor, I think I can say with confidence there will be not one drop of evidence that the parties engaged in concerted activity around that issue. I believe I can say with confidence that the evidence will show the subject never came up in any of the discussions between Schering and Upsher. There was no agreement about that.

Your Honor, Ms. Bokat made a few points that I want to respond to briefly. Listening to her argument, you might have ended up thinking that patents are a bad thing, that they harm consumers. They don't. Patents are in our Constitution, we have laws that provide for them, that provide inventors who get patents with a period of being able to exclude competitors for the purpose of ensuring financial rewards sufficient to incentivise people to spend money inventing things.

There is nothing anti-social about a company that has invented something and gotten a patent on it bringing lawsuits to exclude people who are going to

infringe the patent. There is nothing anti-social about that at all. Indeed, if companies didn't do that, it would produce a disaster for this country, because companies would not spend money on R&D.

Ms. Bokat showed you a number of Schering documents, Your Honor, with projections projecting or exploring what would happen if generic competition came in at a particular time and showing Schering documents that said here's what will happen if generic competition comes in in 1998, here's what will happen if it comes in in 1999. She didn't tell you who created those documents, why they were created or what they mean.

The fact is Schering does projections exploring various kinds of scenarios. Those documents are not and there will be no evidence introduced in this record to show that those documents were an effort to predict the outcome of the Schering-Upsher patent litigation, none. In fact, we'll show that some of those same documents projected generic competition at a particular point in time for a product called Nitro-Dur when we were in litigation with Nitro-Dur and we won it.

And finally, Ms. Bokat used the word "disguise," that Schering was going to disguise payments that it was planning to make to Upsher-Smith.

She used that word in describing a document that she put up on the screen. That's her word. That word is not in the document. And at the end of this case, Your Honor, when you've heard all of the witnesses, I believe Your Honor will find that there was no such effort by anyone at Schering ever.

Finally, Your Honor, I've indicated that Schering plans to prove the various things up on that board. I don't want to lose sight of the fact that the burden in this case is on complaint counsel. They plan, Your Honor, to meet that burden by introducing deposition excerpts and opinion testimony from experts. I would submit that this puts their experts in a very difficult position, because not only is complaint counsel not going to bring the witnesses in, the fact witnesses in, and have them testify before Your Honor, but the experts have never seen them, never even met them, and the experts are going to be rendering opinions, Your Honor, about the intentions of Schering employees that they have never met.

We don't think complaint counsel can sustain their burden in that fashion, and we also submit that when all the evidence is in, Your Honor, when you hear the testimony, the actual testimony, from the people actually involved, that Your Honor will find, as I've

said before, that these settlement agreements were reasonable and that they were not anti-competitive.

Thank you very much.

JUDGE CHAPPELL: Thank you, Mr. Nields.

At this time we will take a lunch recess. We will return at 2:00 p.m.

(Whereupon, at 1:15 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(2:00 p.m.)

JUDGE CHAPPELL: Back on the record, docket 9297.

Would Upsher-Smith like to make an opening statement at this time?

MR. CURRAN: We would, Your Honor.

JUDGE CHAPPELL: Proceed.

MR. CURRAN: Thank you.

Good afternoon, Your Honor.

JUDGE CHAPPELL: Good afternoon.

MR. CURRAN: Your Honor, in this trial, my colleagues and I will prove to you that Upsher-Smith did not engage in any anti-competitive transaction. We will prove that Upsher-Smith did not engage in any sham transaction. We will prove that Upsher-Smith did not trade money for delayed entry. We will prove to you that Upsher-Smith did not manipulate any exclusivity to which it was entitled under the Hatch-Waxman Act, and we will certainly prove to you that Upsher-Smith did not conspire with its bitter rival, Schering-Plough, to assist Schering in developing or maintaining a monopoly in potassium chloride supplements.

Quite the contrary, Your Honor. In this case, we will prove that Upsher-Smith won a very

pro-competitive settlement against a very formidable litigation adversary in Schering-Plough, a company approximately 100 times bigger than Upsher-Smith. That settlement cut more than half of the life off of Schering's patent, and it allowed for generic entry in the year 2001 rather than after the full natural life of Schering's patent, which wasn't -- which will not expire until September 2006.

And, in fact, that's exactly what happened. Generic entry occurred on the first possible date under which Upsher was entitled to come on the market, and that was September 1 of last year. So, as of September 1, 2001, consumers in this country had a generic choice, a generic alternative, to K-Dur 20, and today, Your Honor, there are three -- count them, three -- generic alternatives to K-Dur 20, Upsher-Smith's initial entrant, the Klor Con M20 that you've heard about this morning already, Schering's responsive product, its Warrick generic, and there's a third that you haven't heard about yet, and that's an unbranded generic that's on the market now sold by a company called Qualitest.

Because in keeping with its standard practice, Upsher-Smith licensed its Klor Con M20 to an independent company that now sells in competition to

Upsher's M20, the Warrick generic and K-Dur 20, okay? So, three generic products on the market today, and they're only on the market because of the efforts that Upsher-Smith made and the victory of sorts it achieved in its settlement of the patent litigation with Schering-Plough.

Your Honor, in this case we will prove that Upsher-Smith entered into the settlement in good faith and that it was a bona fide settlement and that it was pro-competitive. We will also prove, Your Honor, that at all relevant times, even before Upsher-Smith entered with its Klor Con M20 generic, it was competing vigorously with Schering-Plough, because Upsher-Smith had other potassium supplements on the market.

The vigorous competition that Upsher-Smith brought to the market with lower-priced alternative products will belie any allegation, any suggestion, any hint that Upsher-Smith was engaged in a conspiracy with Schering-Plough. In short, Your Honor, in the duration of this trial, we will show that Upsher-Smith was, in fact, the consumer's best friend. It fought vigorously for generic entry, it fought vigorously in marketing its lower-priced alternatives, and ultimately the benefits that consumers are enjoying today, well, those consumers are indebted to Upsher-Smith for its efforts

and commitment to bringing those products to market.

Introducing lower-priced generic products is Upsher-Smith's mission, it's its life blood, it's what they do, and it's what they did here, and Upsher-Smith should be heralded as a champion of consumer interests rather than being accused of violating the antitrust laws.

Your Honor, Upsher-Smith is a small, private, family-owned company based in Minnesota, not far outside of Minneapolis. It's an entrepreneurial company. The family that owns it manages it as well. Upsher-Smith was founded many years ago by a gentleman by the name of Frederick Albert Upsher-Smith. That's actually one name, Upsher-Smith. It's not a combination of a merger, a result of a merger between two pharmaceutical giants or anything like that. It's not a made-up name or anything like that. It's the name of an actual pharmacist who started the company.

In 1997, Upsher-Smith had about 250 employees and annual sales of about almost $40 million. Again, that puts it -- that ranks it about 1 percent the size of a Schering-Plough and many of the other major pharmaceutical companies in this country. Given its small size and its virtually nonexistent sales force, Upsher-Smith has always focused on market niches where

it can have an established product and perhaps avoid competing directly with the major efforts and major marketing clout of big pharma.

The potassium supplement area is one in which Upsher-Smith has focused. It's one niche in which it has focused for years, and its product line was modestly successful, certainly successful for a company the size of Upsher-Smith. You've heard discussion today about the variety of products on the crowded potassium supplement market. Upsher-Smith had its share of those. I'd like to show a couple of them to you, Your Honor.

The first is Klor Con 10. This is a 10 milliequivalent product. There have been reference to some others here today. You can see it's a yellow tablet. I'd like to hand one up to you if I may, Your Honor.

JUDGE CHAPPELL: Sure.

MR. CURRAN: Your Honor, this yellow tablet is a wax matrix tablet. If I were to drop it in a cup of water like Mr. Nields did before, it would not dissolve. Other than that, it's about the same product as the K-Dur 20, except you've got to take two of the yellow tablets instead of the big, thick tablet that Mr. Nields showed you before.

In fact, it's kind of interesting that the evidence in this case will show that when most people take a K-Dur tablet, it's too big to go down. So, they split it in half, like I just did with two fingers, and they take it in two parts, basically two 10 milliequivalent parts.

Well, Upsher-Smith did its best for years marketing its wax matrix tablet, 10 mEq, again the K-Dur 20 --

JUDGE CHAPPELL: So, what you have there on the ELMO is a Klor Con 10 --

MR. CURRAN: This -- the white tablet is the K-Dur 20. The yellow tablet is the Klor Con 10.

JUDGE CHAPPELL: Half a dosage.

MR. CURRAN: Maybe I should put 10 -- maybe I should put two of the 10s down so you see a fair match.

Again, Your Honor, the Klor Con 10 is only one potassium supplement that Upsher-Smith was marketing. They were also marketing a very similar product, the Klor Con 8, also wax matrix, doesn't dissolve in water, and, of course, 8 milliequivalent rather than the 10.

Upsher-Smith also marketed and continues to market Klor Con 25 powder that you pour into a liquid and drink, 25 mEq, and a 20 mEq powder. Again, 20 mEq, an exact dosage match to the K-Dur 20. They also

market a bicarbonate, potassium bicarbonate, you drop it in a cup and drink it like Alka Seltzer.

Upsher-Smith marketed these products vigorously and directly against products like K-Dur, they still do, at all times they have. In fact, you will hear testimony that a common promotional theme at Upsher-Smith over the years has been telling pharmacists, take two 10s for the 20. It's cheaper and therapeutically equivalent. With that type of promotional campaign, Upsher-Smith developed a -- as I said, a modest share of the potassium supplement market, but they wanted more. They wanted more share of the market from the K-Dur 20.

So, beginning late 1992, early 1993, they started focusing on developing a generic version of K-Dur 20. They committed resources, they committed time, they committed R&D efforts, and then in 1995, they filed an ANDA for permission from the FDA to market a generic version of K-Dur 20. In accordance with the Hatch-Waxman Act and the other provisions of the law that you're familiar with, they notified Schering-Plough of their intention, and Schering-Plough exercised its right under the Hatch-Waxman Act to sue Upsher-Smith for patent infringement, because as Mr. Nields mentioned before, Schering holds a valid patent

issued by the U.S. Patent & Trademark Office covering the manufacture of its K-Dur 20.

Your Honor, at this time I would like to hand you and other counsel a booklet with some of the documents I'll be referring to, if I may. You'll see the first document in there is the patent, the way it looks when it's issued from the Patent & Trademark Office.

JUDGE CHAPPELL: Are you going to display them on the ELMO?

MR. CURRAN: I may, Your Honor.

JUDGE CHAPPELL: Because if you are, I don't need a copy. I can read those.

MR. CURRAN: Some of them are multipage, so the ELMO doesn't quite cut it. These documents naturally have all been disclosed to counsel earlier.

Your Honor, the first tab is a copy of the official patent issued to Schering-Plough. I include it in there just to underscore that we are dealing with a legitimate -- I think there's no dispute that this is a legitimate U.S. patent giving Schering-Plough the right to exclude competitors from the market for products that use what's disclosed in the patent, the processes.

The second tab, Your Honor, is the complaint

that was filed by Schering-Plough against Upsher-Smith. You'll see that Key Pharmaceuticals is the plaintiff. As you may know and as you will learn during the course of this case, Key Pharmaceuticals is -- was a unit of Schering-Plough and is for all purposes of this case indistinguishable from Schering-Plough, and you can see that this action was filed in December of 1995.

Your Honor, the filing of that action changed the life of the executives at Upsher-Smith. Your Honor, Upsher-Smith had never been involved in a major litigation like what it was beginning to experience in late 1995 and in early 1996. It was forced to stand toe to toe with a deep pocket, big pharmaceutical company, and it found itself engaged in hard-fought, bitter, bare-knuckled litigation.

The first thing that happened in the lawsuit was that Upsher-Smith's litigation counsel, Merchant & Gould, a well-qualified Minneapolis firm, was disqualified for a conflict of interest. Next, a second law firm was disqualified. The third time was the charm, and Upsher-Smith knew it was in a serious fight and retained a fine patent firm in New York City called Fitzpatrick Cella, and you'll be hearing from one of its partners during the course of this litigation. It got expensive, Your Honor. Ultimately,

Upsher-Smith paid nearly $3 million in attorneys' fees. Again, this is for a company whose annual revenues were less than $40 million.

At the outset of the litigation, Upsher-Smith tried to retain some experts who would opine that they were not infringing the Schering-Plough patent. They went to the leading expert in the field, Dr. Gil Banker from Iowa. You'll be hearing from him in this case, where he's a fact witness as well as an expert witness.

Upsher-Smith's counsel provided to Mr. Banker the background materials in the hopes that Dr. Banker would conclude that Upsher-Smith was not infringing the patent and would agree to be their expert witness in the case. Dr. Banker sent back the materials a little while later and said, can't help you, and then showed up on the Schering-Plough witness list and was their expert in that case. That was a bit of a blow to the folks at Upsher-Smith.

Nonetheless, they stood fast and they fought it out, and the litigation continued for 18 months, as I say, at considerable expense, significant executive disruption. We're dealing with a company that's basically got about a half a dozen senior executives. A lot of them were spending an awful lot of their time dealing with matters related to this litigation.

And the litigation was fraught with risk. As I've said, the patent expired -- it still expires -- September 5th, 2006, okay? I've borrowed a chart -- like any good generic company, I borrowed a chart that Mr. Nields used representing the brand name company, and as you can see from this fine display, June of 1997 was when the settlement was entered into. September 2006 is when the patent expires, and Upsher-Smith was able to negotiate a settlement allowing them to enter earlier than the midpoint. If you calculated all the months here, you'd have 110 months, and they were able to enter after 50 months. That was a good deal.

That was a -- June 17th, 1997, was a good day for consumers, because the settlement that was reached on that day allowed generic competition to commence September 1st, 2001, where otherwise, if Upsher-Smith had lost the lawsuit, as it may well have, there would have been no generic competition today, and there wouldn't have been any generic competition possibly until September 2006. Yeah, that was a good day for consumers, and there are a lot of consumers in this country right now who pay less because of that settlement.

Ms. Bokat was showing you a number of charts during her presentation about the benefits of generic

entry. We embrace those charts. We think they prove our point. They prove the benefits to consumers of the early entry.

Ms. Bokat also talked about delayed entry, as though Upsher-Smith had a right to enter the market sometime in late '97 or early '98 or some other time. Un-huh, that's not the way it works. This settlement allowed for accelerated entry by five years. That's what was accomplished on June 17th, 1997.

You've heard reference made and you've been introduced today to Mr. Ian Troup, the president of Upsher. What was in his mind in June of 1997? His company was spending a lot of money defending a patent suit against a deep pocket company. There was a prospect that he would be off the market until September of '06. There was no real end in sight of the litigation. Thirty-eight depositions had occurred. A motion for summary judgment had been filed by Upsher, and the judge did not grant it. Trial was about to start. Who knows when the litigation would have ended?

Frequently you'll hear -- in this case, Your Honor, you'll hear from expert witnesses who say in patent cases like this, often a trial doesn't resolve things. Invariably, there's an appeal to the United States Court of Appeals for the Federal Circuit. Often

there's a remand. Often there's a retrial. Sometimes there's a second appeal, and it can jump up and down like a ping-pong ball in these patent suits.

In fact, we will show in this case, Your Honor, that it's possible, if not probable, that the litigation would have continued for a significant duration and that even if Upsher-Smith had won ultimately, by the time they were able to launch the product, which for reasons I'll explain for a company the size of Upsher-Smith is basically the equivalent of the Invasion of Normandy, gearing up for a launch of a product of this magnitude. So, we will show that even if Upsher-Smith had won ultimately the litigation, it's very likely they wouldn't have gotten a date any earlier than September 1st of '01 to enter the market.

So, why are we here? Why are we here if what -- if the deal Upsher-Smith cut was so good for consumers? Well, I think we're here for one reason, and that's -- and that's because complaint counsel believes Upsher-Smith should have gotten a better deal. Complaint counsel, as you've heard today, complaint counsel's case against Upsher-Smith and their attack on the Upsher-Smith/Schering settlement hinges entirely, as they have candidly acknowledged, on their allegation that the license agreement covering Niacor-SR and other

products and certain manufacturing rights was a sham. Without that element of their complaint and their allegations, they've got no quarrel with that settlement.

But Your Honor will recall, as we've reminded you, that when there was oral argument in this courtroom back in June, I think, when you asked from the Bench complaint counsel's attorney if they had to prove there was a sham in order to win the suit, complaint counsel answered candidly, "Absolutely."

JUDGE CHAPPELL: You may be paraphrasing a little bit, but --

MR. CURRAN: I think the "absolutely" is a quote, Your Honor --

JUDGE CHAPPELL: I'm talking about my part.

MR. CURRAN: I'm sure that's right.

So, let me address now the allegation that the licensing agreement was a sham. Obviously you've heard Mr. Nields address the point, but I want to tell -- I want to tell the tale from Upsher-Smith's perspective. I want to talk about Niacor-SR.

Your Honor, Niacor-SR in 1997 was the crown jewel of Upsher-Smith's research and development efforts. Between 1991 and 1997, Upsher-Smith spent over $13 million in developing Niacor-SR. Again, bear

in mind the size of the company we're talking about. During this period, beginning in 1991, Upsher-Smith's sales were in the $20 millions, and at the end of this period, 1997, as I said before, they weren't even $40 million.

This was the biggest R&D effort Upsher-Smith had ever undertaken. They committed the majority of their entire R&D budget to this product. Much of that money went to conduct nationwide clinical trials on human beings under doctor supervision and so forth like all drugs or almost all drugs have to go through before they will be granted a new drug -- before a new drug application will be approved by the Food and Drug Administration. Hundreds of patients taking it, detailed analysis of the results, doctors and statisticians reviewing the results, reports being prepared and so forth. That's how you get up to $13 or $14 million.

The executives at Upsher-Smith, you'll hear this during the trial, the executives, not the owners, entirely not the owners, the executives gave up end-of-year bonuses voluntarily to contribute to the R&D research fund for Niacor-SR. They had high hopes that Niacor-SR would be a terrific product, a terrific new product, branded product, for Upsher-Smith.

Upsher-Smith planned to build a sales force specifically to sell this Niacor-SR, because they knew that the cholesterol-fighting market in this country and the world is measured in the billions of dollars, not in the millions like the potassium supplement market in this country, but in the billions. You'll be hearing evidence about that, Your Honor. They knew a small share of that pie would be a huge amount of revenues for a company like Upsher-Smith or any other company.

Upsher-Smith was so serious about this product, they developed over several years relationships with leading lipidologists in the country. They helped finance studies of niacin, the use of niacin in fighting cholesterol. They held conferences, flew people in from around the country to Minneapolis to participate in forums debating the use of niacin and particularly slow release niacin. They organized a Blue Ribbon Advisory Committee. They conducted marketing studies. All of this cost money, Your Honor, far from a sham.

They conducted marketing studies, hiring outside consultants to help them refine their approach and marketing technique in selling the niacin product to doctors. Upsher-Smith thought they had a winner

here.

In late 1996, early 1997, Upsher-Smith thought it would be a good idea for them, being that they have no presence overseas at all, not a single human in Europe, they thought it might be a good idea to take this Niacor-SR and maximize its value by finding a licensing partner to market the product in Europe. They engaged a licensing consultant in Europe, in the UK, a company by the name of Moreton, and Your Honor will be hearing about Moreton a fair bit in this case.

They engaged this professional licensing firm to help them identify potential licensing partners in Europe. In the negotiations and even in the written contract with Moreton, which incidentally is in -- in the materials I provided to you under tab 6. In that retainer letter you'll see, and you'll also observe witnesses testifying about this, there is specific contemplation that the license of Niacor-SR will bring initial payments, milestones and royalty income stream.

If you're looking, Your Honor, at tab 6 on the first page toward the bottom, there's a description of the proposed commercial terms for licenses.

You'll also hear testimony and receive evidence, Your Honor, indicating that the specific task of Moreton was to locate a multinational company, a big

pharmaceutical company based in the United States or in Europe that had the capability of taking Niacor-SR and marketing it on at least a European-wide basis if not worldwide non-NAFTA basis. As a fall-back, Moreton was charged with finding specific companies in discrete countries to market the product.

With Moreton, Upsher prepared a marketing plan. It prepared -- they developed a nonconfidential dossier. They sent it around to companies. They got a warm response. Ms. Bokat before was characterizing the response that Moreton had to its marketing efforts as less than strong. We'll prove at trial that Ms. Bokat and complaint counsel are mistaken on that. This was a warm reception. A number of firms immediately responded and wanted confidential detailed information. Five firms met with folks from Upsher-Smith and received a detailed presentation of clinical results. These are big players, too.

And the time frame here, Your Honor -- again, Moreton was engaged in December of '96. By the time it prepared its dossier and marketing materials and sent things out, we're already into late spring. In May and June -- and early June of '97, that's when these marketing efforts were in full swing, and in that period of time, just that period of time, within a --

within -- from the middle of May '97 to the middle of June, Upsher-Smith met with five different multinational companies to discuss Niacor-SR.

The first one was in May of '97, they met at Searle in Chicago. Upsher-Smith had -- sent executives there. They were accompanied by some of the leading lipidologists, Dr. Greg Brown from the University of Washington, who's not an Upsher-Smith employee. He came along to tell Searle how good the Niacor-SR product was and how good -- how important niacin therapy could be to fighting cholesterol. Dr. Claude Drobnes was another outside physician who was part of that presentation team.

After the meeting in Chicago with Searle, Upsher-Smith was invited to and attended meetings with two major pharmaceutical companies in Paris and two in Barcelona. This is in early June. This is days before the deal was cut with Schering-Plough. The reception that Upsher-Smith was receiving from these companies only gave them more enthusiasm and higher hopes for Niacor-SR.

In the meeting with one company in particular, Your Honor, you're going to be hearing a fair bit about this, a French-based pharmaceutical company, today they're a $2 billion company, Pierre Fabre, operations

in the U.S. and many places throughout Europe and the rest of the world. They had their top people there to hear the presentation, and there were discussions of what possible consideration might be required for them to get the rights to Niacor-SR, and they seemed very receptive, Your Honor, to a deal under which they would pay Upsher-Smith $5 million per each country that they were going to be marketing the product in.

Now, Ms. Bokat said there was not an offer of a single dollar for this product before Schering-Plough made the deal with Upsher-Smith. Well, I guess that's literally right, I mean, because the other meetings and so forth didn't materialize into a consummated transaction before the Schering-Plough deal was reached a matter of days later. A product like this, like any product, you can only sell once. Once it's sold, you're not going to run around trying to solicit additional bids and so forth.

You'll hear during the course of this trial, Your Honor, from two executives from Upsher-Smith who were at the meeting with Pierre Fabre, and they can tell you that Pierre Fabre was very interested in this product. They will also tell you that they reported Pierre Fabre's interest to Ian Troup, and they also reported the interest of Searle and the other

companies. So, when Mr. Troup was negotiating with Schering-Plough, he knew that he had alternative buyers out there, and that helped him negotiate a strong deal on the licensing.

Why was there all this interest in Niacor-SR in 1997? Well, a lot of the reason is because of the company Kos that Mr. Nields referred to during his opening statement. As Mr. Nields stated, Kos at the same time as Upsher-Smith was developing an extended release niacin product, and Kos went public in March of 1997. I've got their IPO papers under tab 10.

Your Honor, I certainly don't expect you to read this entire red herring here or perhaps any other time, but I do want to point out that in that initial offering, Kos raised approximately $60 million selling about 30 percent of its stock. So, on a fully diluted basis, that's in the neighborhood of $200 million in initial capitalization.

After the IPO, of course, it was a publicly held stock. Mr. Nields showed you the -- how the stock performed, how it did very well throughout the whole period up until after the Schering-Upsher agreement, but now under tab 11, I have here the market capitalization of Kos, which obviously is the stock price times the number of shares outstanding, and you

can see from this chart that in or around June of '97, Kos had a market capitalization of approximately $400 million. Later it fell, but that was after, well after the deal between Schering and Upsher-Smith.

As Mr. Nields said and as we'll prove at trial, that Kos' valuation was based on the prospects for its Niaspan product. It was a single-drug company at that time.

JUDGE CHAPPELL: What's the difference between Niaspan and Niacor?

MR. CURRAN: You'll hear testimony about that. There's probably no difference. They're both extended release niacin products. They have similar clinical results. In fact, they're so similar, Your Honor, Kos came to Upsher-Smith in early 1997, hat in hand, said, you know, we'd like to buy the patent rights you have covering Niacor-SR, because, you know, we're a little concerned that it might be a problem for us. You'll hear about that, Your Honor.

So, it was in -- it was in this period of early 1997, right through the whole first half of the year, there was a lot of market buzz in the pharmaceutical industry about slow release niacin. Kos' Niaspan and Upsher-Smith's Niacor-SR were wanted commodities out there.

You'll also be receiving evidence, Your Honor, that stock analysts were predicting even greater things for Kos, even after that Kos stock price was hitting the forties, as Mr. Nields was showing you, and even after their market capitalization was approaching half a billion dollars, there were stock analysts out there saying buy it. This niacin thing is the real deal.

In short, Your Honor, in June -- on June 17th, 1997, the prospects for Niacor-SR were very high, and it was perfectly reasonable for Schering to believe that Niacor-SR was going to do well, and it was perfectly reasonable for Upsher-Smith and Mr. Ian Troup to think he had a very wanted product on his hands of considerable value that ought to receive a pretty penny in a licensing deal in Europe.

The licensing transaction on Niacor-SR and certain other drugs that I'll address in a minute was a marriage of interests. Upsher-Smith, as I said, had no marketing capability in Europe or the rest of the world. Schering obviously does. Upsher-Smith had already been looking for a licensing partner, that's what Moreton was doing, and they were looking strictly in Europe, and they were pursuing a multinational that would pay an up-front amount, milestones and royalties. So, when Upsher-Smith and Schering touched upon this

subject, it was a natural, and it happened.

It's interesting, Your Honor, Upsher-Smith thought so much of Niacor-SR, they weren't willing to give up the rights to it for the United States or even Canada or Mexico, because they still envisioned developing the capability of marketing this dynamite product on their own.

Your Honor, Niacor-SR wasn't even the only product in this licensing agreement. Ms. Bokat said before that she thought that the June 17th, 1997 agreement under my tab 4 is probably the most important document in the case. I agree, but I think it's got to be read in full, and when read in full, it becomes apparent that this agreement and the licensing parts of it not only gave Schering-Plough the right to license this Niacor-SR product everywhere in the non-NAFTA countries, it included various other drugs, five in total, that were being licensed from Upsher to Schering-Plough.

Granted, these other drugs did not have hopes on the same level as Niacor-SR, they were generic products, but to a company like Upsher-Smith, that's still significant money, measured perhaps in the tens of millions rather than the hundreds of millions, but that's still real money for a company like

Upsher-Smith.

And perhaps equally important, Your Honor, it wasn't just the licensing of products that was going on in this agreement. There was also the commitment of marketing a -- the commitment of production facilities at Upsher. Your Honor, in this June 17th, 1997 agreement, Upsher-Smith was giving not only Niacor, Prevalite, pentoxifylline and European rights to its potassium supplements. It was also committing to provide production rights at the Upsher-Smith facilities to Schering-Plough at cost. That's on all of the products with a slight modification with regard to Prevalite.

So, if Niacor-SR really hit in Europe being sold by Schering-Plough, Schering under this agreement had the right to force Upsher-Smith to manufacture the product. If it was a real hit, that would have been a significant burden for Upsher-Smith, not only in terms of the expense of the marketing, but it would crowd out certain other Upsher-Smith manufacturing priorities.

My point here, Your Honor, and thanks for indulging if I'm getting into too fine a detail here, but the details of the licensing transaction have to be carefully analyzed and understood from a realistic business standpoint. Complaint counsel hasn't done

that in this case.

JUDGE CHAPPELL: You may continue, Mr. Curran. I would have to be elastic man to reach this water, so go ahead while --

MR. CURRAN: I'd be happy to help.

Your Honor, there was reference made by Ms. Bokat to the negotiations leading up to the licensing and the settlement agreements. Upsher-Smith agrees with what Mr. Nields said, that Schering's counsel responsible for the negotiations, Mr. Hoffman, was ahead of his time in identifying antitrust sensitivities in a transaction like this, but you will hear from every witness in this case who participated in those negotiations that once Mr. Hoffman made clear that he viewed it as a problem if there was any discussion of monetary transactions as part of the settlement as opposed to part of the licensing transaction, that there would be antitrust issues, when he raised that point, Upsher-Smith engaged counsel, brought counsel in to the settlement negotiations.

That counsel, Mr. Nick Cannella, will come here and testify about what he observed in the negotiations of the licensing agreement, and he -- and his testimony will corroborate everyone else who was involved in the negotiations, that there was never any discussion of

delaying Upsher-Smith's right to enter in exchange for money or any other consideration. That just wasn't done. As Mr. Nields said, the entry date for the patent settlement was set and agreed to well before the licensing transaction was negotiated and consummated.

There was no sham here, Your Honor, and there was no payment for delay, and the licensing agreement was not only negotiated fairly with scrupulous attention to antitrust issues, but its terms are fair and reasonable when measured against proper industry standards at the time.

Ms. Bokat also referred to post-agreement conduct. We'd be happy to talk about that, and we'll put on evidence about that in this case. We believe that the parties after June 17th, 1997 acted perfectly consistent with their bona fide intentions going into that agreement. There were numerous communications, discussions, constant dialogue between the companies.

As Mr. Nields pointed out, Niacor-SR did not take off, did not become the product that people had hopes that it would become. Niaspan didn't either, and that's one of the reasons why Niacor-SR didn't make it, but that's -- complaint counsel here, Your Honor, is essentially using the benefit of 20/20 hindsight to second-guess what was a bona fide, legitimate

transaction at the time.

Your Honor, the pharmaceutical industry you will hear from witnesses, fact and expert witnesses, is a risk-fraught industry. Some drugs hit, some drugs don't. It's like the oil industry in Texas. Failure does not mean fraud. In fact, more drugs in development stages, including in Phase III, when we are testing on humans and so forth, more drugs fail than make it.

In this case, Your Honor, you're going to have some expert witnesses put on the stand by complaint counsel who question the bona fides of the people who negotiated the June 17, 1997 agreement, but we will submit that from the comfortable confines of 600 Pennsylvania Avenue or Stanford University in the year 2002 is not a fair way to analyze the reasonableness of intentions back in June of 1997.

Back in June of 1997, when Ian Troup was agreeing to settle the patent litigation on these terms, there was no professor from Stanford whispering in his ear, no, that's not a reasonable date, you really ought to -- you really ought to come in -- insist upon coming in a little earlier. There was no pharmaceutical licensing person from Chicago telling him that Niacor-SR isn't worth what you're about to be

paid for that. This must be a sham.

Ian Troup in June of 1997 was a businessman negotiating a deal. He was advised by counsel. He's an honest businessman, and you'll have an opportunity to size him up yourself, Your Honor. Given all the facts and circumstances surrounding the company at that time, this was a fair, honest and legitimate transaction.

Your Honor, a couple of other points in specific response to things complaint counsel has raised. On the 180-day exclusivity, there's a lot about that in the complaint, Your Honor. You didn't hear a lot about it today so far. There's good reason for that. The allegations of the complaint don't hold up.

It's clear, Your Honor, that no one has been blocked from the market by any exclusivity that Upsher-Smith has. It's also clear that Upsher-Smith did not think it had exclusivity upon the June 1997 agreement.

You will hear undisputed testimony, Your Honor, even from complaint counsel's Hatch-Waxman expert, that the effective regulations at the time, June of '97, said you had to successfully defend the patent litigation to be entitled to the exclusivity.

Upsher-Smith did not successfully defend the litigation; it settled. It settled it. Therefore, under prevailing FDA regulations, it was not entitled to exclusivity at that point in time.

Even complaint counsel's expert will acknowledge that. Now, he will say that he thought -- he thinks of an argument that there was writing on the wall that the 180-day exclusivity would be available to settling parties, but again, that's using 20/20 hindsight. The law in place at the time was a settling party didn't get exclusivity. It was never brought up, it was never discussed in the settlement discussions, and there's not a single term in the June 17th, 1997 agreement that addresses it.

In fact, the June 1997 agreement corroborates our position that Upsher-Smith did not expect to have exclusivity at that time. That agreement again, Your Honor, is under tab 4, and there's a paragraph numbered 3 that Ms. Bokat referred to before. She read only the first sentence about when Upsher-Smith was entitled to accelerate its entry into the market, but then farther down in that same paragraph, there's a sentence that deals with the possibility that Upsher-Smith could come onto the market even earlier if Schering were to grant to any non-affiliate third party a license under the

'743 patent permitting such third party to offer for sale and sell a potassium chloride tablet equivalent to K-Dur M20. In other words, Your Honor, the parties at this time contemplated that there could be other generic entry before Upsher, and this provision was allowing Upsher to accelerate its entry to match the other generic entry.

Another point Ms. Bokat made about this paragraph, she referred to the first sentence where it says, "or any other sustained release microencapsulated potassium chloride tablet." Your Honor, complaint counsel reads that as a limitation, as an undue -- unduly broad limitation on Upsher-Smith's rights to market other products. We'll prove at trial that this provision was specifically negotiated like that because Upsher-Smith wanted it like that, because they wanted to limit -- they wanted to limit the limitation on Upsher-Smith as to what it could and could not market.

This language permits them to market any other product as long as it's not a sustained release microencapsulated potassium chloride tablet, permits Upsher-Smith to market all of its other products that we referred to, including the 20 mEq powder, including the 10 and the 8, which are wax matrix not microencapsulated, including the effervescent 25 mEq,

and any other product that they could develop, even if it's 20 mEq, as long as it doesn't relate to the technology covered by Schering's patent, which covers microencapsulation of tablets.

So, Your Honor, we'll prove at trial that this provision is as constrained as possible, permitting Upsher free reign to market all of its other existing products and permitting Upsher-Smith to develop new products as long as they did not at least arguably infringe the microencapsulation process protected by Schering's patent. And Upsher-Smith did continue to market all of its other products and did continue to market those directly against K-Dur 20 by maintaining its "take two 10s for a 20" promotion.

Your Honor, in short, in this trial, we will provide to you the evidence you need, through live witnesses, through documents, through expert witnesses explaining the industry and the transactions, we'll provide you with sufficient evidence to establish beyond any doubt that the settlement agreement of the patent litigation was bona fide, did not involve any delayed entry in exchange for any consideration.

We will prove to you that the licensing transaction covering Niacor-SR, Prevalite, pentoxifylline, various potassium products and

accompanying production rights were bona fide and fair value. And we'll prove to you what I said at the outset, and that is that Upsher-Smith is a generic company that lives to bring generic -- low-priced generic alternatives to market. That's what it did here.

After we provide all of that proof, Your Honor, we'll ask that the complaint be dismissed against Upsher-Smith.

Thank you, Your Honor.

JUDGE CHAPPELL: Thank you, Mr. Curran.

Is the Government prepared to call your first witness?

MS. BOKAT: Yes, we are, Your Honor.

JUDGE CHAPPELL: Okay, proceed.

MS. BOKAT: I call Dean Goldberg to the stand, please.

Oh, excuse me, Your Honor, a housekeeping matter. We moved the witness' chair this morning --

THE WITNESS: Is that okay?

JUDGE CHAPPELL: Let me swear you in, then we will talk about it. Please raise your right hand.

Whereupon--

DEAN E. GOLDBERG

a witness, called for examination, having been first

duly sworn, was examined and testified as follows:

JUDGE CHAPPELL: Be seated.

MR. CURRAN: May I help by moving the chair, Your Honor?

JUDGE CHAPPELL: Go ahead and sit down in the witness chair.

MR. NIELDS: Your Honor, may I be heard on one housekeeping matter?

JUDGE CHAPPELL: Sure.

MR. NIELDS: Diane Bieri from my firm is going to be handling the cross examination and any objections on this witness. I wanted to introduce her and simply advise the Court that that's why she'll be seated here at counsel table.

MR. CURRAN: Your Honor, if I can make a similar statement, my associate Jaime Crowe will be handling objections and cross examination for Upsher-Smith.

JUDGE CHAPPELL: Okay, thank you.

Ms. Bokat, will you be handling the direct exam?

MS. BOKAT: Yes, Your Honor, I will.

JUDGE CHAPPELL: Tell me again why we moved the chair.

MS. BOKAT: There was a problem -- I can't

remember whether -- oh, I know, so that Your Honor would be able to see the easels during opening statement. The chair was a bit in the way. So, the chair was moved out of the witness box.

JUDGE CHAPPELL: We need to put the chair back where it was in the witness box.

Mr. Curran, is Klor Con 10 dispensed by prescription only? You better take this back.

MR. CURRAN: Yes. You don't have hypokalemia, I guess.

JUDGE CHAPPELL: Hopefully not.

This is better. The witness has been sworn. Would you state your full name for the record, please?

THE WITNESS: My name is Dean Elliot Goldberg.

JUDGE CHAPPELL: You may proceed, Ms. Bokat.

MS. BOKAT: Thank you, Your Honor.

DIRECT EXAMINATION

BY MS. BOKAT:

Q. Mr. Goldberg, by whom are you employed?

A. I'm employed by United Healthcare.

Q. What is the business of United Healthcare?

A. United Healthcare is a managed healthcare company, and basic -- at the most basic level, they're a health maintenance organization or an HMO, which means that we go out and provide -- well, we don't

provide, we pay for health care services for our customers, our customers being employer groups and individuals.

Q. Does that health care include prescription pharmaceuticals?

A. It does for a portion of our membership. United Healthcare manages health care services for approximately 15 to 16 million members. Approximately 11 million of those have a pharmacy benefit under United Healthcare.

Q. Does United Healthcare employ pharmacists to dispense pharmaceuticals?

A. We do not employ pharmacists to dispense medications. We do not own pharmacies, and we do not employ pharmacists who do that.

Q. Does United Healthcare set up networks of pharmacies?

A. United Healthcare works with Merck-Medco, which is our pharmacy benefit management company, to have them set up a pharmacy network on our behalf.

Q. Mr. Goldberg, what is your position with United Healthcare?

A. I serve as vice president of clinical pharmacy management for United Healthcare.

Q. What are your responsibilities in that

position?

A. My responsibilities are to develop programs that help improve the quality of pharmaceutical care received by our members, as well as programs that help manage pharmacy trend. Included in that responsibility is the development and maintenance of our Preferred Drug List, which most people might know as a formulary.

I'm also responsible for working with a group of people that actively manage our $2.7 to $3 billion drug budget.

Q. I'm sorry, was that $2.7 million, with an M, or billion, with a B?

A. Billion, with a B.

Q. How long have you held your current position as vice president of clinical pharmacy management?

A. I was promoted to that position approximately in -- sometime during 1999.

Q. Prior to that promotion, were you employed by United Healthcare?

A. Yes, I actually began my current stint with United Healthcare in 1998 when I actually had a joint position between Pharmacy Management within United Healthcare and also a subsidiary company which then was known as Applied Healthcare Informatics. Applied Healthcare Informatics is the outcomes and economic

research unit of United Healthcare.

Q. Could you explain the function of Applied Informatics?

A. Applied Healthcare Informatics does pharmacoeconomic and outcome research. Because we pay for medical and pharmacy claims, we have a large database that allows us to look at the costs for various conditions, to look at various types of outcomes, like, for example, the incidence of emergency room visits, the incidence of visits to physician offices, ordering of laboratory tests and so on. So, Applied Healthcare Informatics does that research.

Q. What was your responsibility within Applied Healthcare Informatics?

A. Well, again, it was a joint position between Applied Healthcare Informatics and Pharmacy Management, and my role was to identify areas where outcome and economic research would be valuable to pharmacy management in their decision-making process.

In other words, we were interested in looking at more than just the cost of the drug. We were interested in looking at the total cost of care that related to the use of the medication.

Q. Prior to your employment with United Healthcare, had you worked elsewhere in the health care

industry?

A. Yes, I actually began working for United Healthcare I guess in a separate stint in 1989 when I began working for Diversified Pharmaceutical Services, which at that time was the pharmacy benefit management company for United Healthcare. DPS or Diversified Pharmaceutical Services also sold their services to other HMOs, and so I worked for them between 1989 and I believe 1996.

Q. You had mentioned the phrase "pharmacy benefits manager." Would you explain what that is?

A. Yes. A pharmacy benefit manager provides a series of services that help a customer, such as United Healthcare, implement and operationalize a pharmacy benefit. So, for example, they process the claims that get submitted by the individual pharmacies every time a prescription is filled. They provide reporting services so that we can look at where our drug expenditures are going and we can slice and dice the numbers to be able to tell what we spend money on. They provide programs and tools to help manage the pharmacy benefit.

They also set up the system that allows us to administer the pharmacy benefit by telling which of our -- which of the people that fill a prescription are

actually eligible members in our book of business or -- versus members which are not eligible for us to handle the claims.

Q. What positions did you hold with Diversified Pharmaceutical Services?

A. I began with them as a manager of pharmacy programs, and my responsibility there was to basically help each customer develop their formulary and to implement programs that helped manage their pharmacy costs. I later became director of drug information services, where I was responsible for the development of all of the clinical documents that were used for the development of DPS's formulary as well as the development of all of our customers' formularies.

Q. Have you held any other positions in the health care industry?

A. I have held three other positions. One of them is the year period between my time at DPS and the time I went to -- back to United Healthcare where I spent a year as director of research for the Alignment Diabetes Centers, and prior to my time at DPS, I was employed by Abbott Northwestern Hospital as assistant director of pharmacy services responsible for the clinical programs of that hospital pharmacy. Abbott Northwestern Hospital was a 750-bed tertiary care institution in

Minneapolis. And the other final position that I held was as assistant professor of pharmacy practice at the University of Minnesota College of Pharmacy.

Q. Do you hold any educational degrees?

A. I do. I have a Bachelor of Arts in journalism. I have a Doctor of Pharmacy degree from the University of Minnesota, and I did my -- much of my undergraduate work in pharmacy at the University of Arizona but did not receive a degree there. I transferred to the University of Minnesota where I got my Doctor of Pharmacy degree.

Q. Are you a registered pharmacist?

A. Yes, I am.

Q. Mr. Goldberg, you mentioned a United Healthcare formulary. What is the title of that document?

A. We call it a Preferred Drug List.

MS. BOKAT: Your Honor, I have a document that was labeled CX 55 for identification that I would like to hand to the witness if I may and to the Court, because I would like to examine the witness about this exhibit.

JUDGE CHAPPELL: Has it been admitted?

MS. BOKAT: It has not. My intention was to ask the witness to identify it and then offer it in evidence and then proceed to some questions.

JUDGE CHAPPELL: All right, that's fine, as long as he doesn't read into the record from a nonadmitted exhibit, he can identify it, yes.

BY MS. BOKAT:

Q. Mr. Goldberg, do you have CX 55 there?

A. Yes.

Q. What is that document?

A. This is a photocopy of the member version of our 2002 Preferred Drug List.

MS. BOKAT: Your Honor, I would like to offer, please, into the record CX 55.

MR. CROWE: No objection, Your Honor.

MS. BIERI: No objection, Your Honor.

JUDGE CHAPPELL: CX 55 is admitted.

MS. BOKAT: Thank you, Your Honor.

(Commission Exhibit Number 55 was admitted into evidence.)

BY MS. BOKAT:

Q. Mr. Goldberg, how often is this Members Preferred Drug List published?

A. The printed copy is printed or produced once a year; however, the online version is updated approximately every one to two months.

Q. When in the course of a calendar year is the printed version produced?

A. It's produced sometime between the beginning of November and -- maybe the end of October and the beginning of December.

Q. What is the purpose of the Preferred Drug List?

A. Well, the Preferred Drug List is just what it suggests. It's a list of drugs, and for our membership, you have to look at the Preferred Drug List and consider the benefit, the pharmacy benefit, that our members have or that most of our members have, and that benefit is a three-tiered co-pay designed benefit. And the reason I'm describing that is because it's important to understand that the three tiers really comprise three different co-pay levels, such that if a physician wrote a prescription for any generic drug, all generic products are classified at the first tier and are also classified as preferred or being on the Preferred Drug List.

Brand name drugs that are on the Preferred Drug List are also -- the members pay a slightly higher co-pay or second tier co-pay for brand name products on the Preferred Drug List, and for brand name products that are not on the Preferred Drug List, they pay the highest co-pay or a third tier co-pay. So, the Preferred Drug List really defines what the members' out-of-pocket expectations are.

Q. Currently, what is the amount of the co-payment in those three tiers?

A. In the year 2001, our average co-payment was approximately $7 for a generic drug; it was approximately $12 to $15 for a preferred brand name drug; it was approximately $26 for a nonpreferred brand name drug.

Q. What are the amounts of the co-payment in the year 2002?

A. In 2002, we increased those co-payment levels, and the first tier co-payment is in the range of $7 to $10; the second tier will range between $15 and $25; and the third tier will range between $30 and $50.

Q. Why did United increase those tiered co-payments?

A. We did so because it's one method of managing a pharmacy benefit for the people who hire us to do that, and so as the price of drugs go up and as we try and keep the members' out-of-pocket contribution toward the cost of the benefit, we try and keep it in the range of 30 to 35 percent. So, to achieve that, you know, that percentage out-of-pocket experience, we increase the co-pay levels to meet that expectation.

Q. How do pharmaceuticals become listed on the Preferred Drug List of United Healthcare?

A. Well, I'll describe the scenario for say a new brand name drug that was just approved by the FDA, but before I do that, I'll say again that all generic products -- once a product becomes generically available, it's automatically added to the Preferred Drug List. It doesn't undergo any review or scrutiny. It's automatically added to the list.

A new brand name drug would first be reviewed by a committee of physicians and pharmacists, called the National Pharmacy and Therapeutics Committee, and the purpose of that committee is to outline salient clinical points about the medication and to define whether the drug is a must add, a must not add or a may add product.

A drug that would be a must add is a drug where there really was no previous therapy to treat a given condition or the new drug is so unique that there's no reason that it shouldn't be on the Preferred Drug List. We've never actually made a decision on a drug as a must not add, but that would be a drug with a black box warning, which means it has severe side effects, or it's an antiquated drug and no longer used in clinical practice to a wide degree.

A drug that is a may add is a medication that is similar to other drugs on the marketplace, and a

decision to add it to the Preferred Drug List could be based on factors other than clinically. Any medication that develops or that gets a may add vote from the National P&T Committee then goes to a separate committee called the PDL Management Committee, and what they do is they entertain considerations such as cost, marketplace factors and other considerations into a final decision as to whether the drug goes on or not.

Q. If a branded drug is on your Preferred Drug List, does anything happen once the generic becomes available?

A. If a drug is -- if a branded product is on our Preferred Drug List and it loses patent and a generic becomes available, the generic automatically is added to the Preferred Drug List. The brand name product remains on the Preferred Drug List until such time as Merck-Medco, which is our PBM, assigns a MAC or a maximum allowable cost to that drug. A maximum allowable cost is the maximum amount that we will reimburse a pharmacy for that generic product.

Once Medco assigns that MAC value, which they generally do quickly after the availability of a generic, then the brand name version moves to the third tier and the generic version remains at the first tier.

Q. When you say the branded product at that point

moves to the third tier, would you explain that, please?

A. The brand name product becomes nonpreferred, so it moves off of the Preferred Drug List, but if our members want access to it or if a physician prescribes it, our members would have access to it, although at the highest co-pay level.

Q. What determines whether Medco will add a drug to this maximum allowable cost list?

A. Well, according to Medco, they MAC 98 to 99 percent of all drugs available generically, and what leads them to MAC a drug generally is if there are no clinical reasons to not MAC it or if there are -- and/or if there's widespread availability of that generic product. So, for example, if a generic manufacturer came out with their generic product but it was only available in one part of the country, not everywhere, Medco generally won't MAC that drug, because there's not enough product in the marketplace to have it be available across the country.

Q. What is the purpose of maintaining a MAC list?

A. The purpose of placing a MAC on a drug relates to the fact that for many generic products, there's a wide range in the cost of those individual generic products. If you take a drug, as an example,

amoxicillin, a common antibiotic, I don't know how many generic manufacturers there are of amoxicillin, but at least a dozen if not twice that many. The range in cost of a pill of generic amoxicillin might range between a couple of pennies a tablet all the way up to a dollar a tablet. So, the purpose of setting a maximum allowable cost or a MAC on the drug is to drive the pharmacies to purchase the lower costing generic products and to dispense those lower costing generic products, which allows them to make their profit but also it allows us to not have to pay for the more expensive generic product versions.

Q. In your business experience, have you observed the impact of generics on related branded drugs?

A. I'm not sure I understand the question fully. Are you asking what happens to the generic drug or the branded drug once a generic comes on the market?

Q. Yes.

A. Okay. Typically what happens when a generic hits the marketplace is the market share at least in our book of business, amongst our 11 million members, the market share of the branded version goes from 100 percent down to the range of 20 to maybe 25 percent, meaning that within the first one to two months after a generic comes on the marketplace, 75 to 80 percent of

that particular drug is dispensed as the generic version, whereas a small percentage remains as the branded version.

Q. What typically happens to the price of the branded product once there's a generic?

A. I'm not aware that anything happens to the price of the branded product.

Q. So, does the branded price remain -- the branded product remain at the same price typically?

A. Typically it does.

Q. Once a second generic product becomes available, what typically happens to the price of the generics?

A. Well, as more --

MR. CROWE: Objection, Your Honor, overbroad.

THE WITNESS: Generally, as more generics --

JUDGE CHAPPELL: Hold on, Mr. Goldberg. When there's an objection, let me rule first.

Would you repeat the question?

MS. BOKAT: Once there is a second generic product on the market, what happens to the generic price?

JUDGE CHAPPELL: I'll overrule that.

Can you answer that, sir? Is that clear enough?

THE WITNESS: Yes.

JUDGE CHAPPELL: Go ahead and answer. I've overruled it.

THE WITNESS: As more generics enter the market, generally the price of the generics go down. So, as the second, third and fourth generic manufacturer enters the marketplace, typically the cost of those generics tend to continue to go downward.

BY MS. BOKAT:

Q. Do you know why retail pharmacies dispense generics in place of the brand name product?

MS. BIERI: Objection, Your Honor, that calls for speculation.

JUDGE CHAPPELL: Well, actually, the question only asked him a yes or no answer, so I overrule the objection until I hear the answer.

MS. BOKAT: And I'll try to reiterate the question.

JUDGE CHAPPELL: Are you going to withdraw the question and restate it, Ms. Bokat?

MS. BOKAT: I better do that, because I'm not sure I can repeat it word for word.

JUDGE CHAPPELL: Okay.

MS. BOKAT: So, thank you, Your Honor, I'll withdraw and start again.

BY MS. BOKAT:

Q. Do you know why retail pharmacies dispense generics? And the question now is just do you know.

A. Yes, I think I do.

Q. Why do retail pharmacies dispense generics?

A. Retail pharmacies dispense generic products because they tend to make more money on those generic products than when they dispense a branded version of the -- of the drug. Companies like ours also offer an incentive to pharmacies to dispense generic products in the form of a higher dispensing fee.

Q. Why does your company offer that incentive to retail pharmacies?

A. Well, because generics really represent one of the most powerful ways that we can help manage pharmacy costs, and so we want to do whatever we possibly can to promote the use of generics, not only because it costs us less, but because it costs our members less who pay less out of pocket when somebody dispenses a generic product.

Q. Within United Healthcare's book of business, how does the cost of generic drugs compare to the price of branded drugs?

A. When you look at the data from 2001, the average cost of a generic drug was approximately $12 to

$13 per prescription. The average cost of a branded drug was in the range of $63 to $65 per prescription.

Q. Does United Healthcare do anything to try and encourage the use of generic drugs?

A. Well, absolutely. I think the biggest tool that we use is the three tier benefit design, which incents members to choose generic drugs. Educating physicians about that co-pay differential also incents them to allow their patients to receive a generic when it's available.

We also provide a report to our members that defines -- we send the report to members who are getting branded versions of drugs where there's a generic available, and the report defines, number one, that there's a generic option for you, and then it describes the cost saving to the member, their out-of-pocket expense, if they were to switch from the branded version to the generic version.

Q. Is there anything else that United Healthcare does to encourage the use of generic drugs?

A. Outside of incenting the pharmacies with the higher co-pay, with the higher dispensing fee, not that I can think of. The one -- well, let me take that back.

We work with Merck-Medco, who has a program

called Generics First, and that program basically puts generic samples in physician offices so that when the physician sees a patient and he or she goes to the sample cabinet to pull out a medication, the physician can then pull out a generic sample instead of a brand name product, and that program has been demonstrated to be fairly successful in reducing costs.

Q. Why does United Healthcare encourage the use of generics?

A. Well, again, part of our business we are at risk for. In other words, our customers, the employer group, pay us a set amount of money, and we then pay for that employee's health care. If we spend more than the employer gives us, we lose money, and so one way to control the spiraling cost of pharmaceuticals is to promote the use of generic products, because as I described earlier, on average, a $12 or $13 drug is much less expensive than a $60 to $70 drug, and so it represents a greater value not only to us but to the member who has to pay a lower co-pay and also to the employer, who by keeping their drug costs down can help reduce the increase in premium from year to year.

Q. If generic utilization in your book of business increases, do you know what the dollar impact of that is on United Healthcare's drug spend?

A. Yes, actually, for every 1 percent increase in generic utilization that we experience, we reduce our costs by $9 to $10 million.

Q. I'd like to -- we've been talking about generics. I'd like to shift topics now to focus on potassium chloride supplements.

Mr. Goldberg, do you know how potassium chloride supplements are used to treat patients?

A. I do.

Q. How are potassium chloride supplements used to treat patients?

A. Potassium is used to treat a condition known as hypokalemia or low potassium levels. So, if a patient were to have a low potassium level, you would give either oral or intravenous potassium to bring that potassium level back up into the normal range.

Q. What is the impact on the human body of low potassium levels?

A. Well, the side effects of low potassium really depend on how depleted the body is of potassium, but with mild losses, you can experience side effects or effects, stuff like muscle pain, fatigue, weakness, and as the potassium levels continue to go down, those symptoms get more severe such that you would experience a more severe form of fatigue, the peripheral muscles

get very, very weak, even to the point of in severe low potassium levels, you could become actually paralyzed, you could have difficulty breathing, and again, with very severe low potassium levels, your heart can develop abnormal rhythms, and those things can ultimately lead to death.

Q. Is there any group of patients in whom you typically see low potassium levels?

A. The most common group of patients that have low potassium levels are people who take diuretics, certain types of diuretics to treat their high blood pressure or their congestive heart failure, and the diuretics themselves -- not only do they lower blood pressure, but they cause you to lose potassium, and so you need to take potassium supplementation to keep your potassium levels, again, in the normal range.

Q. Are there potassium chloride supplements on United Healthcare's Preferred Drug List?

A. Yes, there are.

Q. Do you know approximately how many potassium chloride supplements there are on your Preferred Drug List?

A. I'm guessing between 12 to maybe 15 or 16 products.

Q. Why is that number of potassium chloride

supplements on United Healthcare's Preferred Drug List?

A. Well, the different products that are on the list really relate to the dosage form of the potassium. So, for example, we have liquid potassium, we have effervescent tablets, we have tablets and we have capsules of potassium chloride. We also have a couple dosage forms of potassium that are not the chloride form, but they're a different salt of potassium, which those particular drugs might be used to treat low potassium levels of different etiologies or different natures.

I guess the reason that we have that degree of choice in that category is because patient need varies highly between one person to another such that say, for example, you have an elderly person who can't swallow a tablet very easily, a liquid preparation may be good for that person or an effervescent tablet or, you know, a tablet that can dissolve in water. Other people prefer to take capsules over pills or pills over capsules. So, really, anything to enhance patient acceptance and willingness to take the product is important.

Q. Is K-Dur 20 on United Healthcare's Preferred Drug List?

A. Yes, it is.

Q. Why is K-Dur 20 on the Preferred Drug List?

A. Well, the K-Dur product has a couple of characteristics that make it an advantageous product. I guess one of those is that the way the K-Dur works is it's a -- what they call a microencapsulation, so there are little tiny potassium particles that are microencapsulated, and when you take the pill, that pill disintegrates rapidly, but the small little spheres of potassium continue to release that potassium as it travels through the intestine over an eight to ten-hour period of time.

An advantage of that product is that it may not cause as much GI irritation as some other forms of potassium pills or capsules. Another reason that K-Dur is important is, at least as far as I'm aware, it's the only 20 milliequivalent strength available in this country, and so for the people who take or need higher doses of potassium, they would have to take fewer pills to get the same dose.

Q. You referred to GI irritation from some potassiums. Can you explain what that GI irritation is that you referred to?

A. Well, potassium in and of itself is an irritant to the stomach, and there's a thought that some pills which are contained in a wax matrix, it's just the

design of the pill, when that pill is sitting in the lining of the stomach, it's releasing potassium into the stomach, and that high concentration of potassium at that site is at least thought to contribute to some of the higher upset of the stomach or GI irritation that you see in potassium products.

Q. Is there a generic of K-Dur 20 available in the United States today?

A. Yes.

Q. Is the branded K-Dur 20 nonetheless still on United Healthcare's Preferred Drug List?

A. As of today, it is not.

Q. At some point, was K-Dur 20 taken off the Preferred Drug List?

A. At the time Merck-Medco MAC'd K-Dur 20, the generic product remained available in the first tier and on the Preferred Drug List, and the branded version of K-Dur 20 -- I'm sorry -- yeah, K-Dur, the branded version of K-Dur 20 became nonpreferred.

Q. So, in which co-payment tier does branded K-Dur 20 fall now?

A. It would fall in the third tier or the highest co-payment level.

Q. Do you know when Medco MAC'd the generic of K-Dur 20?

A. It was sometime in October of 2001.

Q. Since the generic of K-Dur 20 became available, what has happened to utilization of K-Dur 20 within United Healthcare's business?

A. Well, currently approximately 75 to 80 percent of the 20 milliequivalent microencapsulated potassium product is dispensed as the generic. The remaining about 20 percent, maybe 25 percent, that -- of people that are still getting the brand name version.

Q. Do you know how long it took for generic utilization of the generic of K-Dur 20 to reach this 75 to 80 percent level?

A. Certainly within the first one to two months after the generic form was available, that transformation occurred in that time period.

MS. BOKAT: That concludes my direct examination, Your Honor.

JUDGE CHAPPELL: Okay, thank you, Ms. Bokat.

Who is going to proceed first? It's up to you. Do you want me to choose?

MR. CURRAN: No, I think by agreement Upsher will proceed first with this witness, Your Honor.

MR. CROWE: Excuse me, Your Honor.

CROSS EXAMINATION

BY MR. CROWE:

Q. Good afternoon, Dr. Goldberg. How are you? Welcome to Washington.

A. Hi.

Q. Dr. Goldberg, you mentioned that Merck-Medco is UHC's PBM, correct?

A. Yes.

Q. And, in fact, Merck-Medco has been UHC's PBM for about two years now, correct? Roughly.

A. Sounds -- yes, about -- approximately the middle of 2000.

Q. Now, another function that Merck-Medco performs for UHC as UHC's PBM is that it helps negotiate volume purchase discounts with pharmaceutical manufacturers on behalf of UHC, correct?

A. Yes.

Q. And a volume purchase discount is simply another word for a rebate, right?

A. Yes.

Q. And it's a rebate that a pharmaceutical company will give to Merck-Medco, right?

A. Yes.

Q. And Merck-Medco will then pass that rebate along to United Healthcare, correct?

A. Part of it, yes.

Q. Part of it. It will keep part of that rebate;

it will pass part of the rebate along to UHC, correct?

A. Yes, um-hum.

Q. And these rebates are for UHC -- are for drugs that run through the UHC pharmacy system, correct?

A. Yes.

Q. Now, pharmaceutical manufacturers may provide rebates in exchange for access to UHC's formulary, correct?

A. I'm not sure I would frame it exactly that way, but suffice it to say when a drug gets added to our Preferred Drug List, if the manufacturer's offering a rebate, that occurrence would allow us to receive those rebates.

Q. They also -- you may also get more rebates if you have an enhanced market share, correct, or if the company has an enhanced market share, correct?

A. In some cases, although I'm not privy to the specifics of the contracts that Medco holds.

Q. All right. So, in some cases, as the pharmaceutical manufacturer's market share increases, then the discounts that it offers may actually get bigger, correct?

A. Yes.

Q. Now, Merck-Medco has contracts with several pharmaceutical companies, correct?

A. Yes.

Q. And one of the pharmaceutical companies with which it has a contract is Schering-Plough, correct?

A. Yes.

Q. And Merck-Medco's contract with Schering provides for rebates to Merck-Medco for Schering's products, correct?

A. Yes.

Q. Now, Merck-Medco, when it gets a rebate for a Schering product, is then able to pass that rebate along to UHC or part of the rebate, correct?

A. Yes.

Q. And there's nothing wrong with rebates, right? Rebates are good for UHC?

A. In general they are.

Q. And they are good for UHC's customers, correct?

A. Yes.

Q. And that's because you can reduce the costs of pharmaceutical products that way, right?

A. The cost of brand name pharmaceutical products.

Q. And it provides an economic incentive to lower pharmaceutical costs, correct?

A. Yes.

Q. Okay. Let's discuss the term or let's discuss MACing for a moment. You alluded in your direct

testimony to how Merck-Medco can MAC a drug, correct?

A. Yes.

Q. And MAC is simply a maximum allowable cost. That's what MAC stands for, correct?

A. Yes.

Q. And it's the maximum cost or the maximum amount that UHC will reimburse a pharmacy when they dispense a generic drug, correct?

A. Correct.

Q. So, if Merck-Medco MACs a generic product, the generic is then preferred, correct?

A. No, actually, the generic is preferred at the time it becomes available. Medco's MACing it has nothing to do with the status on our Preferred Drug List.

Q. But at the point that it gets MAC'd, then it becomes -- the generic becomes preferred?

A. No, the generic becomes preferred at the time it's approved by the FDA and available on the market -- in the marketplace.

Q. Can you see this document, Mr. Goldberg?

A. Yes.

JUDGE CHAPPELL: You can see it, but can you read it?

THE WITNESS: Reasonably well.

BY MR. CROWE:

Q. Do you recall that I asked you a question at your deposition on October 26th of 2001, and I asked you this question:

"When a generic drug becomes available, is the brand name drug -- let me rephrase that. If you have a brand name drug on your Preferred Drug List and then a generic becomes available for that brand name drug, does the brand name drug come off the Preferred Drug List?

"ANSWER: It depends." You continue to answer, "If the generic drug is MAC'd by Merck-Medco -- MAC refers to the maximum allowable cost -- that's the amount that we reimburse the pharmacy when they dispense a generic drug. If Medco MACs the drug, then the generic, of course, is preferred, and the brand then moves off the list and becomes non-preferred. If the generic drug is not MAC'd, then the branded version, if it was on the list before, would remain on the list and would remain preferred. If it was non-preferred, it would also remain preferred (sic)."

Do you remember giving that answer, Mr. Goldberg?

A. Yes. The last line says that it would also remain non-preferred.

Q. Now, if Merck-Medco does not MAC the generic drug, then the branded version that was on the list before would stay on the list, and it would remain preferred, correct?

A. Correct.

Q. Now, you mentioned one reason why Merck-Medco might decide to MAC a drug, and that -- and that's if there's an insufficient supply of the generic drug, right?

A. That's why they would not MAC a drug.

Q. Well, there are two reasons why they would MAC a generic drug, right? One of the reasons is if the pharmaceutical product itself is a narrow therapeutic index drug, right?

A. That's one reason why they potentially might not MAC it.

Q. Right. In other words, there's a concern about a difference in blood levels between the generic versus the brand name product?

A. Right.

Q. Right? And there's a concern that there might be some clinical outcome as a result. In other words, that it could be bad for the consumer in some way, correct?

A. Yes.

Q. And by the way, potassium chlorides are not considered to be low therapeutic index drugs. Is that correct?

A. They are not considered to be narrow therapeutic index drugs.

Q. Now, there's a second reason why Merck-Medco might not MAC a generic drug, right, and that's if the net of rebate costs --

JUDGE CHAPPELL: Hang on a second. You asked the question, and then you proceeded to another question. Let the gentleman answer before you proceed to another question.

MR. CROWE: Yes, Your Honor.

BY MR. CROWE:

Q. There's another reason why Merck-Medco might decide to not MAC a generic drug, correct?

A. Yes.

Q. And that second reason is that the net of rebate cost of the branded product remains lower than what UHC would have to pay for the MAC'd generic, correct?

A. Yeah -- yes, that's true.

Q. So, in other words, the branded manufacturer may discount their branded product to such an extent that the product is actually cheaper than the generic

drug even at the MAC rate, correct?

A. I believe that's correct.

Q. So, the existence of a generic doesn't necessarily mean that the generic is cheaper than the brand, correct?

A. There are some circumstances where that's not -- where that is true.

Q. And, in fact, there may be circumstances in which the generic drug may be close in price to the generic -- to the brand drug, correct?

A. I guess you'd have to define "close."

Q. Well, the difference in cost between the generic and the brand may not be that great.

MS. BOKAT: Objection, Your Honor. I think that was vague.

JUDGE CHAPPELL: Mr. Goldberg, do you have enough information to answer the question?

THE WITNESS: Well --

JUDGE CHAPPELL: Let me rule. I will sustain it, because I think it's vague also. Can you restate the question, please?

BY MR. CROWE:

Q. The price difference between -- the cost of a generic drug versus a branded drug to UHC, there may be -- there are circumstances -- there may be

circumstances in which that price difference is not that great, that the price between the two may be pretty close or the cost.

MS. BOKAT: Objection, Your Honor. I think he's basically restated the question again saying "not that great," which is again ambiguous.

JUDGE CHAPPELL: After hearing the question again, Mr. Goldberg, can you answer it?

THE WITNESS: I can respond to it, and my response would be that --

JUDGE CHAPPELL: Then hang on, okay, then I'll overrule the objection and let's let him answer it if he thinks he can answer.

THE WITNESS: My response would be that even a 10 to 15 percent difference is significant on a drug that has high volume of use.

BY MR. CROWE:

Q. Now, if a drug, Dr. Goldberg, is not on the formulary, it still remains available to UHC's members, correct?

A. Correct.

Q. It's just that it's available at the highest co-pay level, as you testified earlier, correct?

A. Correct.

Q. Now, Merck-Medco also provides another service

to UHC, and that is that they track formulary compliance rates, correct?

A. Yes.

Q. And the formulary compliance rate is approximately 92 percent for UHC, correct?

A. Yes.

Q. Incidentally, some UHC members actually choose to purchase brand name drugs even after a generic is available and even though they may have to pay a higher co-payment. Is that correct?

A. Yes.

MR. CROWE: Your Honor, may I approach? I have an exhibit I would like to hand you at this time.

JUDGE CHAPPELL: Yes, thank you. Has this exhibit been admitted?

MR. CROWE: I'm sorry, Your Honor?

JUDGE CHAPPELL: Has this exhibit been admitted into evidence?

MR. CROWE: No, I am going to move for the admission into evidence.

BY MR. CROWE:

Q. Mr. Goldberg, do you see this document, which is entitled 2001 Preferred Drug List with United Healthcare at the top?

A. Yes.

Q. And it contains USX 277 at the very bottom of the page. Do you see that?

A. Yes.

Q. And you recognize this document, right? This is UHC's PDL for 2001, correct?

A. It's the physician version of our Preferred Drug List.

Q. And it's actually -- it's actually excerpts from the physician's version of the PDL, correct?

A. Yes.

Q. And does your document contain four pages?

A. Yes.

Q. And it begins with UHC 105 and ends with UHC 108?

A. Yes.

MR. CROWE: Your Honor, at this time I move for the admission of USX 277 into evidence.

JUDGE CHAPPELL: Any objection?

MS. BOKAT: No, Your Honor.

JUDGE CHAPPELL: USX 277 is admitted.

(USX Exhibit Number 277 was admitted into evidence.)

BY MR. CROWE:

Q. Sir, could you please turn to the second to the last page of this exhibit. Are you on the page where

at the right-hand side of the page it says, "Electrolytes, 15.3"?

A. Yes.

Q. Now, the designation of "Electrolytes, 15.3" is actually a therapeutic designation assigned to this list by Merck-Medco, correct?

A. Yes.

Q. And do you see right below that, you have three columns, and one column is for generic name? Do you see that?

A. Yes.

Q. Another column for brand name. Do you see that?

A. Yes.

Q. And then there's another column for relative cost. Do you see that?

A. Yes.

Q. And right below that heading, we have another entry which is 15.3.1, Potassium. Do you see that?

A. Yes.

Q. And that's a sub-designation, a therapeutic sub-designation also assigned to this list by Merck-Medco, correct?

A. Yes.

Q. So, all of the products on this list are

potassium products, correct?

A. Yes.

Q. And if you look at this list, it starts with -- it starts with liquids, right?

A. Yes.

Q. It also contains sustained release tablets, right?

A. Yes.

Q. Sustained release capsules, right?

A. Yes.

Q. Effervescent tablets, do you see that?

A. Yes.

Q. And powders, do you see that?

A. Yes.

Q. Now, before I get -- before we get into this list, I just want to ask you a few questions about potassium products in general.

First of all, they're not a major focus for UHC, correct?

A. They're not in the top 20 or 30 therapeutic classes, no.

Q. Well, but they're not a major focus of UHC.

A. Correct.

Q. In fact, most of UHC's clinical activities involve the top 50 or so therapeutic classes, right?

A. Yes.

Q. And potassium products don't fall into the top 50 or so therapeutic classes, correct?

A. Correct.

Q. In fact, potassium products are probably not even in the top 100 therapeutic classes, right, or if they are, they are about the bottom 100, correct?

A. They're probably somewhere between 50 and 100. I don't know exactly where they fall.

Q. Okay. Now, let's go back to the list. This list of potassium products in all of these different forms are classified within the same therapeutic subclass on the formulary, right?

A. Yes.

Q. And they're all products -- potassium products that are therapeutically equivalent, correct?

A. They're all therapeutically equivalent in that they increase potassium levels.

Q. Well, they are therapeutically equivalent, correct?

A. Yes.

Q. All right. Now, let's take an example, all right? Let's say a doctor prescribes a 20 mEq potassium supplement, all right? Do you see there's a potassium -- there's a potassium chloride 20 mEq

supplement on the list, right?

A. Yes.

Q. A doctor could prescribe two of the 10 potassium chloride mEq products, correct?

A. Yes, that's correct.

Q. And if a doctor does that, it's going to have the same effect -- prescribing the two 10 mEq tablets is going to have the same effect as prescribing one potassium chloride 20 mEq product, right?

A. That would be true assuming that the patient continued to take multiple tablets.

Q. Well, sure, but if the patient complies obviously.

A. Right.

Q. But otherwise, the benefit is going to be the same, correct?

A. Right.

Q. Now, UHC, by the way, hasn't done any research to determine whether prescribing two of the 10 mEq potassium chloride tablets would be cheaper than prescribing one of the 20 mEq potassium chloride tablets, correct?

A. That -- that is correct. I don't know if it's more or less expensive for two 10s than one 20.

Q. And that's because United Healthcare hasn't

undertaken any specific research about that, correct?

A. Right.

Q. Now, there's nothing on this formulary that would prevent a plan member from going to a doctor and asking for a cheaper alternative to this potassium 20 mEq product, right? Nothing in your plan would prohibit that, right?

A. Correct.

Q. And there's nothing in your PDL that would prevent a doctor from prescribing a cheaper alternative to the K-Dur product, right?

A. Right.

Q. And there's nothing in your plan that would prevent a pharmacist from simply calling up a physician and asking whether it's okay to substitute K-Dur for a cheaper alternative, right?

A. Correct.

Q. Now, let's focus on the products on the list for a moment. First of all, I see -- let's start up at the top with liquids, all right, and I see that there's a plus sign next to KCl 10 percent. Do you see that plus sign?

A. Yes.

Q. And if you look at the bottom or to the bottom of the page, there's a legend, right?

A. Yes.

Q. And according to that legend, the plus sign means, "Use generic, brand not preferred," right?

A. Yes.

Q. Do you see that?

A. Um-hum.

Q. So, if there's a plus sign, we know that there has to be a generic product, right, otherwise you wouldn't be saying use generic, right?

A. Correct.

Q. So, going back to the top, under Liquids, for potassium chloride 10 percent, we know there's a generic because there's a plus sign, and we know that there's at least one brand name, right, because you have a brand name listed, Kayciel or Kaclel elixir. Do you see that?

A. Yes.

Q. And I may be mispronouncing the name.

A. You are.

Q. How do you actually pronounce it?

A. Kayciel.

Q. Kayciel, thank you.

Now, Kayciel may not necessarily be the only brand, because the brand names that are listed here aren't necessarily intended to be exhaustive, right?

A. Yes, they are intended to be examples of the generic form of 10 percent KCl liquid.

Q. So, for any of these different categories of potassium products, there may be more brand name drugs than are actually listed. Is that right?

A. Yes.

Q. All right. Going back to KCl 10 percent, we know that there's a generic because of the plus sign, and we know that there's at least one brand name, maybe more, so I am going to put a two next to that.

Let's go down to the next category. We have potassium gluconate, do you see that?

A. Yes.

Q. That also has a plus sign, so there's a generic, right?

A. Yes.

Q. And we know that there's at least one brand, and that's Kaon.

A. Yes.

Q. I'm going to put a two there.

Let's go to sustained release tablets, and the first product that's entered there is KCl 8 mEq. Do you see that?

A. Um-hum.

Q. We know there has to be a generic, because

there's a plus sign there, right?

A. Yes.

Q. And we know that there's at least one brand, right, because there's Slow K?

A. Yes.

Q. And by the way, just because there's a plus sign doesn't mean there's just one generic. There may be more than one generic, correct?

A. That's correct. A plus sign indicates that the drug really is MAC'd, and the brand is nonpreferred, the generic's preferred.

Q. Sure, but it doesn't speak to the number of generics that are actually available, correct?

A. No, it doesn't.

Q. Now, let's go to the next product, which is KCl 10 mEq. Do you see that?

A. Yes.

Q. There's a plus sign, so we have at least one generic, and it looks like there are one, two, three brands listed, right?

A. Yes.

Q. So, I am going to put a four there.

Next we have KCl 20 mEq, and there is no plus sign there, this is the 2001 formulary, and we know that the brand is K-Dur, right?

A. Yes.

Q. But now we know that there's actually a generic version of the 20 mEq product, right?

A. Yes.

Q. But for purposes of this, let's just put a one there for right now.

Let's go next to sustained release capsules. Do you see that?

A. Yes.

Q. We have potassium chloride 8 mEq. Do you see that?

A. Yes.

Q. And there is no plus sign, so it doesn't appear, at least as of the publication of this PDL, that there was a generic version of this product, right?

A. I don't know that that's true.

Q. There's -- well, there's no plus sign, right?

A. Well, it's not MAC'd. There may be a generic available.

Q. But we don't know that just from this information.

A. I don't know that.

JUDGE CHAPPELL: Hang on, let's talk one at a time. This lady is trying to take everyone down.

THE REPORTER: I need to go off the record for a moment.

(Pause in the proceedings.)

BY MR. CROWE:

Q. We were at KCl 8 mEq. There is no plus sign there, so we don't know whether there was a generic simply based on the PDL, correct?

A. Correct.

Q. But we do know there was at least one brand, right, and that's Micro-K 8 mEq, right?

A. Right.

Q. Let me put a one there.

The next is KCl 10 mEq. There's a plus sign there, so we know there's at least one generic, correct?

A. Correct.

Q. And we know that there's at least one brand, Micro-K 10 mEq, right?

A. Correct.

Q. There may be more brands, correct, we just don't know based on this list, right?

A. Right.

Q. And then we have effervescent tablets, and we have effervescent potassium. Do you see that?

A. Yes.

Q. There's a plus sign, so we know that there's at least one generic, right?

A. Yes.

Q. And we know that there's at least one brand, K-Lyte, right?

A. Yes.

Q. I am going to put a two there, and actually I am going to go back up here and put a two there.

Let's go down to powders. We have potassium chloride sustained release. There's no plus sign, so we don't know whether or not there's a generic, but we know that there is at least one brand, right?

A. Yes.

Q. Micro-K LS, right?

A. Yes.

Q. Let's put a one there.

And the same for the next entry, potassium bicarbonate, K-citrate. We don't know whether or not there's a generic, but we know that there's at least one brand, right, K-Lyte DS?

A. Yes.

Q. Let's put a one there.

Next we have potassium bicarbonate, KCl calcium carbonate. There's a plus sign, so we know that there's at least one generic, right?

A. Yes.

Q. And we know that there's at least one brand, correct?

A. Correct.

Q. So, let's put a two there.

Next we have powdered potassium, and that has a plus sign, so we know that there's at least one generic, right?

A. Yes.

Q. And we know that there are at least two brands, because there are two brands listed here, KLor and KLor Con EF, right?

A. Yes.

Q. So, let's put two there for that one.

Finally we have potassium bicarbonate calcium chloride --

MS. BOKAT: Excuse me, Your Honor, would it be possible to move that page up so that we could all read it on the monitor? I don't think the --

JUDGE CHAPPELL: He will need to move it up if he wants the witness to read it.

MR. CROWE: Thank you, Your Honor.

BY MR. CROWE:

Q. The last entry is potassium bicarbonate, CALC-CHL. It doesn't appear that there's a generic

brand of that product, at least based on this PDL, right?

A. Correct.

Q. But we know that there's at least one brand, right?

A. Right.

Q. So, let's put a one down on that.

Now, if you add all of these up, at least by my calculations, and my math isn't always very good, I count that there are 24 different potassium products available, right?

A. There are not 24 different potassium products. There are 24 different combinations of brand and generic named potassium.

Q. And that's at a minimum, because we know that there might be more generics than we were assuming and we know that there might be more brands than were actually identified on the PDL, correct?

A. Correct.

Q. Now, back in October, on October 26th of 2001, when we met in Minneapolis, you thought that K-Dur 20 had always been preferred on UHC's PDL, correct?

A. Yes.

Q. All right. And, in fact, as of October 1st, 2001, K-Dur was still on UHC's PDL, right?

A. Um-hum, yes.

Q. And at that time -- at the time of your deposition, you didn't realize that Klor Con M was a generic version of K-Dur. Isn't that right?

MS. BOKAT: Objection. What Mr. Goldberg said in his deposition isn't relevant here.

JUDGE CHAPPELL: Your objection is relevance?

MS. BOKAT: Yes, Your Honor.

JUDGE CHAPPELL: Overruled.

MR. CROWE: Thank you, Your Honor.

BY MR. CROWE:

Q. As of the time of your deposition on October 26th of 2001, you did not realize that Klor Con M was a generic version of K-Dur, correct?

A. Correct.

Q. And as of the time of your deposition on October 26th, 2001, you didn't believe that UHC was considering whether or not to list Klor Con M as a product that would be available to its members on the PDL, correct?

A. Correct.

Q. Could I turn your attention to CX 55. Do you still have that, Mr. Goldberg?

A. Yes.

Q. And this was the online version of UHC's PDL as

of October 1st of 2001, correct?

A. I don't know where it came from. I'm assuming that it was the online version given that it's listed in print down here.

Q. This is the same exhibit that was -- that you saw at your deposition, correct?

A. I don't remember.

Q. Is there anything that would help you to remember whether or not this is the same exhibit that you saw during your deposition? If I showed you your deposition transcript with the exhibits, would it help you remember?

A. Well, I guess I'll have to trust that this is the document I saw in that deposition.

Q. Okay. You don't have any reason to believe that it's not?

A. No.

Q. All right. Now, this 2002 PDL, this online version, included changes through October 1st of 2001, correct?

A. Yes.

Q. Could you turn to the ninth page of this exhibit, and I'm sorry, but it looks like the pages are not numbered, so we may have to count. What I'm looking for is at the top it should say 2002 Preferred

Drug List, and then there's a list of drugs, and it's A through D.

JUDGE CHAPPELL: There are numbers in the lower right corner.

MR. CROWE: Thank you, Your Honor. Of course, the copy I have does not have numbers, so bear with me. We're looking at page 22178.

THE WITNESS: Okay.

BY MR. CROWE:

Q. The drugs that are listed on this page and a few pages that follow are preferred drugs, correct?

A. They are preferred commonly prescribed brand name drugs that are on the Preferred Drug List.

Q. And if you turn a few pages, about three pages, to page 22181 -- are you there?

A. Yes.

Q. -- you'll see that K-Dur is one of those drugs that's listed on the Preferred Drug List, right?

A. Yes.

Q. All right. Now, let's go back a few more pages, and if you would, please turn to page 22186. Do you see that?

A. Yes.

Q. And this list here is of brand name drugs with generic alternatives, right?

A. Yes.

Q. Now, turn to page 22191. Are you there?

A. Yes.

Q. Okay. K-Dur is not listed on this list, correct?

A. Correct.

Q. If it were, it would fall between Kaon and Keflex, correct?

A. Yes.

Q. So, as of the time that this PDL was on the internet, it didn't indicate that there was a generic alternative to K-Dur, correct?

A. Correct.

Q. Okay.

Your Honor, I have one more exhibit, if I may approach the witness.

JUDGE CHAPPELL: Okay.

BY MR. CROWE:

Q. Mr. Goldberg, do you have what has been marked as USX 1001 in front of you?

A. Yes.

Q. This is the 2002 drug list that was printed off of the internet this morning. Do you recognize this document?

A. Yes.

Q. Now, today's January 23rd, 2002. The PDL that we just saw, which was CX 55, was current as of October 1st, 2001. The PDL, the online PDL has been revised since October 1st of 2001, correct?

A. I don't believe it has.

Q. Wasn't it your testimony that the online PDL is revised after every PDL Management Committee meeting?

A. Yes.

Q. And your testimony was also that the committee meets every other month, correct?

A. Yes.

Q. The PDL was last revised on October -- on October 1st of 2001. Now, about three months have elapsed. This should have been revised, correct?

A. It should have been, but I don't know for sure if it has been.

Q. All right. Could you -- and unfortunately, this one is definitely not numbered, so could you please turn to what is the 11th page, which says 2002 Preferred Drug List, D-N?

MS. BOKAT: Was counsel planning to offer this in evidence or was it in evidence already?

MR. CROWE: Your Honor --

JUDGE CHAPPELL: It's not been offered.

MR. CROWE: Your Honor, at this time I would

move to enter this document into evidence.

JUDGE CHAPPELL: Any objection?

MS. BOKAT: No, Your Honor.

JUDGE CHAPPELL: It appears to be the same thing as CX 55; however, I -- it's a colored copy of -- we will let the witness tell us if there's any difference, but USX 1001 is admitted.

(USX Exhibit Number 1001 was admitted into evidence.)

BY MR. CROWE:

Q. All right, do you have the -- are you on the 11th page?

A. I'm right there, yes.

Q. Okay. Now, in Exhibit CX 55, which was the version that was current as of October 1st of 2001, if you will turn to that for a minute, you will see that K-Dur appears at the top of the document. Do you see that? You can look on the screen.

A. Yes.

Q. All right. Now, in this version, under the same list, Preferred Drug List, K-Dur appears toward the bottom of the list. Do you see that?

A. Yes.

Q. So, it's very likely that this has been revised since October 1st of 2001, correct?

A. Yes.

Q. K-Dur is still listed on the Preferred Drug List, right?

A. Yes.

Q. Now, could you turn to the 21st page, and the page that I'm looking for, at the top it will say, "Brand Name Drugs with Generic Alternatives, E through K." Are you there?

A. Yes.

Q. All right. So, this lists, as it says, brand name drugs that have generic alternatives, correct?

A. Yes.

Q. And this is intended to inform plan members and physicians whether or not there is a generic alternative to a brand name, correct?

A. Yes.

Q. All right. Could you turn the page, let's go to the next page, and let's go to the bottom. Do you see where it says Kaon?

A. Yes.

Q. And beneath that, it says Keflex, right?

A. Yes.

Q. K-Dur is still not listed as a brand drug with a generic alternative, right?

A. Yes.

Q. And this is the PDL that's online as of January 23rd of this year?

A. Yes. Can I make a point about this document?

Q. We'll get to that in just a minute.

A. Okay.

Q. Sir, you've never personally treated in the last eight years anybody with any potassium deficiency problems, correct?

A. That's true.

Q. You're not a physician, right?

A. That's true.

Q. You didn't go to medical school?

A. That's true.

Q. Now, you have never been retained as an expert witness to discuss potassium products, correct?

A. That's correct.

Q. And you've never written any articles about potassium products and their uses, correct?

A. That's correct.

MR. CROWE: Thank you very much. At this time, I have no more questions, Your Honor.

JUDGE CHAPPELL: Thank you.

Schering?

MS. BIERI: I just have a few questions, Your Honor.

JUDGE CHAPPELL: Proceed.

CROSS EXAMINATION

BY MS. BIERI:

Q. Hello, Dr. Goldberg.

A. Hi.

Q. I'd like to re-introduce myself to you. We met at your deposition, but I'm Diane Bieri. I'm here on behalf of Schering today.

You know that there are a variety of 10 milliequivalent potassium chloride products on the market today, correct?

A. Yes.

Q. And there have been a variety of 10 mEq potassium chloride products on the market for a number of years, correct?

A. Yes.

Q. Do you know the share that generic 10 mEqs held of UHC's new potassium chloride prescriptions in August of 2001?

A. No, I don't.

Q. And do you know the share that K-Dur 20 held of UHC's new potassium chloride tablet and capsule prescriptions in August of 2001?

A. I happened to look at K-Dur as a drug before I came here.

Q. Um-hum.

A. And I can tell you that the 10 and 20 milliequivalent dosages of that represent approximately 30-some percent of our potassium prescriptions.

Q. As of when?

A. I believe that was year to date August 2001.

Q. And I believe you said that you don't know the share of the generic 10 mEqs represented at that time, correct?

A. I do not.

Q. So, you don't know if the generic 10 mEq share was the same size as the share that the K-Dur product held, correct?

A. That's -- I do not know that.

Q. Now, we went through a number of brands of different generic and branded products for potassium chloride on your formulary, correct?

A. Yes.

Q. And I would just like to go through a couple more products with you that may not be on your formulary. Do you know that Schein makes a generic powder for potassium chloride?

A. They may.

Q. And how about Rugby generic powder potassium chloride, have you heard of that brand?

A. Not specifically.

Q. What about the Warner-Chilcott generic wax matrix potassium chloride tablet, have you heard of that?

A. I'm not familiar with the specific generic manufacturers of each dosage form of potassium chloride.

Q. Okay, but you'll agree with me that there are a number of generic manufacturers who make different dosages of potassium chloride tablets, correct?

A. Yes.

Q. And not all of them are listed specifically on your formulary, right?

A. We don't list generic manufacturers. We just list that they're available generically.

Q. Okay. In some states, I think you mentioned that in some states pharmacists substitute potassium chloride product -- generic products for the branded products, correct?

A. Yes.

Q. And in fact, in some states, pharmacists are required by law to substitute the generic for the branded product unless the doctor orders otherwise, correct?

A. I don't know that.

Q. Have you -- do you have any understanding at all that there are some laws which require substitution of generic products over branded products?

A. I am not aware of it as being a law.

Q. But it is a common practice in the industry that unless a doctor prescribes to dispense as written, in some cases the pharmacist will substitute, correct?

A. That's correct, if the doctor does not write DAW or dispense as written, the pharmacist will often times substitute the generic product.

Q. And the generic company doesn't need to spend money on advertising its product in order to achieve that -- the substitution by the pharmacist, right?

A. That's true.

Q. And a generic company doesn't have to spend money on a sales force to go promote its products to doctors in order to get doctors to prescribe its generic, right?

A. That's true.

Q. Now, you are aware that Schering and Upsher were involved in a lawsuit over Schering's patent on the K-Dur product, correct?

A. Yes.

Q. And you know that Schering and Upsher settled that lawsuit, right?

A. Yes.

Q. And you know that as part of the settlement, Schering permitted Upsher to bring its generic onto the market before the expiration of Schering's patent, right?

A. I believe you told me that at our deposition.

Q. If Schering had gotten an injunction in that lawsuit preventing Upsher's generic product from coming onto the market until 2006 when its patent expired, would Upsher's product be on the market today?

MS. BOKAT: Objection, speculation.

JUDGE CHAPPELL: Response? Any response?

MS. BIERI: No, Your Honor.

JUDGE CHAPPELL: Sustained. Move on.

MS. BIERI: I have nothing further, Your Honor. Thank you.

JUDGE CHAPPELL: Any redirect based on the cross exam?

MS. BOKAT: A few points, if I may, Your Honor, about Upsher's cross examination.

JUDGE CHAPPELL: Okay.

REDIRECT EXAMINATION

BY MS. BOKAT:

Q. Mr. Goldberg, toward the end of Mr. Crowe's examination, when he was showing you one of the

Preferred Drug Lists, you said you wanted to make a point. He said we would get to that later. I'd like to get to that now. Was there a point you wanted to make?

A. Yes, the -- as we looked at the different versions of the Preferred Drug List, we obviously are in error by not listing K-Dur as being generically available. The fact is that the drug file, which is the electronic system against which claims are processed, does reflect K-Dur as being a nonpreferred product and the generic as being the preferred product, and when generic K-Dur is dispensed, it is reimbursed at the -- at a MAC level.

Q. Could you explain what this electronic file is?

A. Yes, when a pharmacy fills a prescription, they type the information into a computer. The computer sends the claim to Merck-Medco. Merck-Medco checks that claim against a whole bunch of different things, things like member eligibility, is the drug covered, what's the co-payment amount and so on and so on. So, it's that electronic file that reflects whether a drug is preferred or nonpreferred.

It also tells the pharmacy back what the member's co-payment is, and it also lets the pharmacy know how much they'll get reimbursed for the product.

Q. So, today, when a pharmacy enters this electronic file about K-Dur, will the electronic file tell the pharmacist that K-Dur, the brand, is no longer preferred?

A. Yes.

Q. Will the electronic file tell the pharmacist in which co-pay tier K-Dur -- the branded K-Dur falls?

A. Well, it will pass back the co-payment for brand name K-Dur. So, if a pharmacist filled a prescription for K-Dur, it would pass back a co-payment that would reflect a third tier co-payment for that member.

Q. Does the electronic file signal the pharmacist what the tiered co-payment would be if he or she dispensed the generic for K-Dur 20?

A. Well, again, the file doesn't tell the pharmacist tier one, two, three, but it would pass back a first tier co-pay amount.

Q. You were talking with Mr. Crowe about the 10 milliequivalent potassium chloride products. Has United Healthcare ever encouraged physicians or patients to use two 10 milliequivalent tablets in lieu of a 20?

A. No, we haven't, and we do not promote the need for people to take multiple tablets when one tablet

will do, the reason being that, number one, it's more of a hassle for members to take two tablets than it is to take one, and while he asked a question about whether I've engaged in specific research to show that there's less compliance if people take two tablets versus one, I believe I said I hadn't looked at specific research to show that that's the case with potassium, but we do know in general that as people take more tablets, their compliance goes down. So, our interest is in making it as easy for our members as possible, and we do not really intend for them to take multiple tablets when one would do.

MS. BOKAT: Thank you, Your Honor. Thank you, Mr. Goldberg.

JUDGE CHAPPELL: Recross based on the redirect?

RECROSS EXAMINATION

BY MR. CROWE:

Q. Sir, when did you become aware that the internet version of the PDL was wrong?

A. Just now.

Q. Okay. So, you hadn't focused on it before today?

A. Well, I believe at the deposition you indicated that K-Dur was still preferred, and I believe at that time I told you I didn't know what the status of the

brand and generic versions were.

Q. Does UHC also plan to offer the Qualitest potassium product as an alternative for its plan members?

A. I don't know what Qualitest is, so I can't comment on that.

MR. CROWE: Thank you, Your Honor, no further questions.

MS. BIERI: Nothing from Schering, Your Honor.

JUDGE CHAPPELL: Okay, Mr. Goldberg, I have a couple questions.

Do you know what the percentage of market share of the United States HMO market United Healthcare has?

THE WITNESS: I do not know that.

JUDGE CHAPPELL: Could you tell me if it's over or under 50 percent?

THE WITNESS: It's under 50 percent.

JUDGE CHAPPELL: Do you have an estimate of what share of the U.S. healthcare market, not just HMO, but U.S. health care market that you have?

THE WITNESS: Can I go back? In your first question, did you ask what percent of all of the people in managed care do we have or all --

JUDGE CHAPPELL: Right, right.

THE WITNESS: I'm certain that it's under 50

percent.

JUDGE CHAPPELL: Do you know of anyone larger than United Healthcare who does what you do?

THE WITNESS: I believe Aetna is larger.

JUDGE CHAPPELL: And my other question, not just managed care, but U.S. health care, do you have an idea of what percentage of the market you cover?

THE WITNESS: Of everybody in the United States?

JUDGE CHAPPELL: Right.

THE WITNESS: Well, assuming there's approximately 250 million people in the country and we manage approximately 15 million or 16 million, it's 7 or 8 percent.

JUDGE CHAPPELL: Okay. You were questioned from USX Number 277, which is the 2001 Preferred Drug List. I think you described that as the doctor's version?

THE WITNESS: Yes.

JUDGE CHAPPELL: Do you know as you sit here today whether the latest version of this -- by the way, is there a newer version of this?

THE WITNESS: Yes, there's a 2002 version.

JUDGE CHAPPELL: Do you know if the doctor's version of the 2002 Preferred Drug List has K-Dur

generic listed?

THE WITNESS: I don't know off the top of my head.

JUDGE CHAPPELL: And you testified that it was being prescribed as generic. Tell me again how that's happening if it's not on the preferred list.

THE WITNESS: Well, because pharmacies automatically, you know, whenever a generic becomes available, pharmacies will just by the nature of their business dispense the generic, and I can look in our claims system for the year 2001 and see that the generic form of K-Dur has been dispensed.

JUDGE CHAPPELL: Okay. Another question, you're a registered pharmacist, right?

THE WITNESS: Yes.

JUDGE CHAPPELL: Are you a pharmacologist?

THE WITNESS: No.

JUDGE CHAPPELL: Do you know what a pharmacologist is?

THE WITNESS: Yes.

JUDGE CHAPPELL: Tell us.

THE WITNESS: A pharmacologist is a person who specializes in the study of pharmacology, which deals with things like mechanism of action and how drugs work and how they interact in the body.

JUDGE CHAPPELL: You have had some pharmacology training in pharmacy school?

THE WITNESS: Yes.

JUDGE CHAPPELL: I heard you say that if a doctor prescribes 20 mEq, then you could give two 10 mEqs. Is that right?

THE WITNESS: Yes.

JUDGE CHAPPELL: Is that really going to have the same effect or the same time-release effect if the doctor says one 20 mEq per day, every 24 hours? If I take two 10s, aren't they released within 12 hours or are they going to release in the same amount of time as one 20 mEq over a 24-hour period?

THE WITNESS: Well, let's go back, and the first part of your question was could you automatically substitute two 10s for a 20, and the answer to that is no, a physician would have to write a separate prescription saying take two 10s instead of the one 20.

JUDGE CHAPPELL: So, a pharmacist couldn't do that; it would have to be done by the doctor.

THE WITNESS: A physician would have to write a new prescription.

JUDGE CHAPPELL: Okay.

THE WITNESS: Would they have the same effect? Yes, in all likelihood, you know, you're basically

giving 20 milliequivalents of potassium in the form of two tablets, and those tablets are released in the form of K-Dur over an eight to ten-hour period of time. So, you would expect them to deliver the same amount of potassium or a relatively close amount of potassium over that eight to ten-hour time period.

JUDGE CHAPPELL: Okay. Just so I'm clear, the 20 mEq versus the two 10s would effectively release about the same time?

THE WITNESS: Yes.

JUDGE CHAPPELL: That's all I have.

Do counsel have any follow-up questions based on my questions? Complaint counsel?

MS. BOKAT: Nothing from complaint counsel, Your Honor.

JUDGE CHAPPELL: Okay. Upsher?

MR. CROWE: Nothing from Upsher-Smith, Your Honor.

JUDGE CHAPPELL: Schering?

MS. BIERI: No, Your Honor.

MR. CROWE: Are the parties prepared to call your next witness or do you want to wait until tomorrow?

MS. BOKAT: With the Court's indulgence, we would prefer to wait until tomorrow.

JUDGE CHAPPELL: That was our original understanding. We did finish a little early. Remember tomorrow we start at noon. We will start at 9:30 on Friday.

Let me point out that when you have a document, when you're introducing an exhibit that wasn't introduced before, you need to give an original to the court reporter or as close as you have to an original exhibit.

All right, anything further? We're in recess until 12:00 noon tomorrow. Thank you.

(Whereupon, at 4:50 p.m., the hearing was adjourned.)

C E R T I F I C A T I O N O F R E P O R T E R

DOCKET/FILE NUMBER: 9297

CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

DATE: JANUARY 23, 2002

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: 1/24/02

SUSANNE BERGLING, RMR

C E R T I F I C A T I O N O F P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

DIANE QUADE